

2013

AMCP GUIDE TO

Pharmaceutical Payment Methods, 2013 Update



VERSION 3.0

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Academy of
Managed Care
Pharmacy®

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About AMCP: AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's nearly 7,000 members develop and provide a diversified range of clinical, educational, and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit. For more information about AMCP, visit www.amcp.org.

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Executive Summary

The methods by which the U.S. health care system pays for prescription drugs are changing because of

- Growth of healthcare as a percentage of GDP.
- Healthcare reform (The Patient Protection and Affordable Care Act, known as PPACA).
- Payer demands for price transparency.
- Increasing cost sharing by patients.
- The belief by many stakeholders that prescription drug prices and price increases should be moderated.
- Increasing Generic Dispensing Rates.
- Increase in specialty pharmaceuticals on the market, their increasingly high cost per course, and increasing specialty pharmacy penetration and utilization (in both the pharmacy and medical benefit).
- Undisclosed prescription drug rebates and discounts which may differ by type of purchaser.

The current debate about prescription drug payment methods centers on determining the most appropriate basis for calculating how payers, including patients, government agencies, employers, and health plans, should pay pharmacies and other providers for dispensing prescription drugs and providing pharmaceutical services. Historically, payment for prescription drugs has been based on published prices that do not necessarily reflect the actual acquisition costs paid by providers, primarily pharmacies, physicians, and hospitals. This has led policymakers to believe that Medicare and Medicaid programs have paid more than is necessary for prescription drugs. The reality is much more complex, confounded by the two necessary components of a reimbursement formula: estimated ingredient cost and dispensing fee. Currently, reimbursement of the ingredient cost often subsidizes the dispensing fee, which can be confusing and which may generate calls for more transparency.

Thus, in an effort to reform the payment system and reduce drug expenditures, policymakers have made significant and proposed changes to the benchmarks used by public programs to pay for drugs, and, in some cases, have created new benchmarks altogether.

Federal government activity to reduce drug expenditures via payment system changes was a component of healthcare reform. PPACA included these changes that impact drug payment and payment methodologies:

- *Increased minimum Medicaid drug rebates* to 23.1% of the Average Manufacturer Price (AMP) for single source drugs, 13% of AMP for non-innovator multiple source drugs, and

17.1% of AMP for blood clotting factors, all per unit or the difference between the AMP and the best price per unit and adjusted by the Consumer Price Index-Urban (CPI-U) based on launch date and current quarter AMP.

- *Cap on total rebate amount for innovator drugs* to 100% of the AMP
- *Additional Medicaid Line Extension rebates* for oral solid dosage forms of single source or innovator multiple source drugs (e.g., new formulations such as extended release).
- *Extended Medicaid rebates to cover Medicaid patients* in managed care organizations.
- *A new formula for calculating the Federal Upper Reimbursement Limit (FUL)*
- *New definitions of AMP and multiple source drug.*
- *Expanded eligibility for Public Health Service 340B discounts.*
- *An FDA approval pathway for biosimilar biological products* and Medicare Part B payment that would incentivize their use.

Private payers have followed the government's lead but have not aggressively ventured out on their own to change their payment methods and benchmarks. As of the publication date of this *Guide*, AWP and manufacturer-determined Wholesale Acquisition Cost (WAC) remain widely used payment benchmarks for private insurance reimbursement to pharmacies, physicians, and other providers. It is unclear how replacement of the AWP benchmark might affect provider payment for two reasons: (a) no widely available alternative benchmark has been selected, and (b) pharmacy benefit manager contracts with network pharmacies often include language to adjust payment under any new benchmark to maintain comparable pricing to the AWP standard. Despite the pushback on using AWP, this much-maligned benchmark continues to be available from a variety of sources.

Bundling of outpatient prescription drugs into payment for selected diagnoses and procedures is being tried on an expanded basis by Medicare for renal dialysis, hospice and on a limited, voluntary basis with Integrated Delivery Networks and some private payers. However, the tradition for outpatient treatment continues to be that drugs are a pass-through cost to be charged at the providers' actual or estimated acquisition price plus a pre-determined markup.

The U.S. drug purchasing and distribution system is complex and involves multiple transactions among myriad of stakeholders, including drug manufacturers, distributors, Group Purchasing Organizations, government entities, third-party payers, pharmacies (retail, mail order, specialty), pharmacy benefit managers, physicians, and patients. Changes in

payment methods or benchmarks, and laws impacting pricing to government entities and government-specified entities, have significant implications for all stakeholders, affecting the payments and prices to and from each of these groups. Knowledge of the intricate distribution and payment systems for prescription drugs is essential to ensure that payment reform results in desired outcomes including fair and equitable payment to providers while avoiding unintended consequences such as reduced access to medically necessary drugs.

AMCP recognizes the need to help stakeholders and policymakers better understand, evaluate and navigate the profound changes occurring in payment for prescription drugs in the United States. This 2013 update to the 2009 AMCP Guide to Pharmaceutical Payment Methods¹ offers a comprehensive examination of the methods and price benchmarks that have been used in the public and private sector to pay for pharmaceuticals in the United States, the changes that have occurred or are likely to occur in the future, and the forces that are behind these changes. AMCP has made every effort to make the *Guide* an unbiased presentation of information, issues, and implications.

Following the introduction (Section I), the *Guide* is presented in four main sections covering the following subject areas:

Payment Benchmarks. Section II explains the drug payment benchmarks that have come into use over the past four decades, how and when they are used, and how they compare to one another. The benchmarks discussed in detail are those that have the greatest overall impact on pharmaceutical payment or are currently receiving the most scrutiny and discussion, including average wholesale price (AWP), average sales price (ASP), average manufacturer price (AMP), wholesale acquisition cost (WAC), maximum allowable cost (MAC) also referred to as maximum reimbursement amount (MRA), federal upper limit (FUL), national average retail price (NARP), and national average drug acquisition cost (NADAC).

Payers and Payment Methods. Section III describes payment methods used by payers as well as manufacturers' price concessions related to product preference and acquisition across various settings of care such as community pharmacy, mail service pharmacy, physician offices, clinics and hospitals. Discussed in this *Guide* are: Public payers such as Medicare, Medicaid, the Department of Defense, the Veterans Administration, and the Public Health Service's 340B program; private payers such as commercial insurers, self-funded employers and individual patients; intermediaries including managed care organizations and pharmacy benefit managers; and providers such as hospitals, physicians, pharmacies and home health providers. Also covered are topics relevant to private health insurance, including benefit design, the use of formularies

by private payers, and the relationship of these factors to the availability of rebates from drug manufacturers.

How Products, Services, and Payments Flow Through Channels of Distribution. Section IV provides a detailed analysis of how drugs are purchased, distributed, and paid for by various entities within the pharmaceutical supply chain in the U.S. The purpose of this section is to examine the complexity of the drug distribution system as well as the multiple direct and indirect transactions that occur.

Select Issues and Implications for Stakeholders. Section V explores the issues and implications of the most significant changes to drug payment methods or benchmark prices that have been proposed or implemented in recent years. The topics evaluated in this section include actual acquisition cost (AAC) and the surveys used to determine NADAC and NARP; the use of weighted average AMP for calculation of federal upper limit (FUL); the implications of ASP+6% payment under Medicare Part B; pricing transparency; the role of comparative-effectiveness research; orphan drugs; and bundling of provider payment for prescription drugs with payment for other related services.

Highlights

The following are discussed in this *Guide*. Please refer to the corresponding section in the *Guide* for a more detailed discussion of trends in drug pricing and payment.

■ ■ Payment Benchmarks

Health plans cover pharmaceuticals under the "medical benefit" (typically drugs administered in a medical office or clinic setting, or administered through home health), and the "pharmacy benefit" (typically drugs dispensed by a retail, mail order or specialty pharmacy). Pharmaceuticals covered under the medical benefit and/or the pharmacy benefit component of a health plan typically have differing payment methods and use different pricing benchmarks.

Average Wholesale Price and Wholesale Acquisition Cost

Historically, AWP has been the generally accepted drug payment benchmark for most payers, primarily because it is current and readily available. However, in recent years AWP became recognized as a "sticker price" that does not reflect the average wholesale price ultimately paid after subtraction of undisclosed price concessions.

AWP is related to WAC, although not by a standard multiplier. Historically, the relationship of AWP to WAC has been most commonly, though not always, characterized by one of the

following equations, as determined by the publisher: $AWP = 1.20 \times WAC$, or $AWP = 1.25 \times WAC$ for branded pharmaceuticals. While multiple source generic drugs may have WACs from which AWP can be calculated, their reimbursement is typically based instead on maximum allowable cost.

However, WAC is not reflective of an actual acquisition cost for a wholesaler, because the WAC does not include discounts and price concessions that are offered by manufacturers. For sole-source branded pharmaceuticals, WAC more closely approximates the price that pharmacies pay to manufacturers or wholesalers than does AWP and, for this reason, often serves as the basis for discounts and rebates negotiated between manufacturers and private payers (i.e., discounts and rebates are typically based on WAC) for both medical and pharmacy benefit drugs. Manipulation of the so-called “spread” or differential between WAC and AWP has been the subject of lawsuits against pharmaceutical manufacturers and publishers alleging “gross inflation” of AWP for certain drugs and has led to the discontinuation of publishing or to a dramatic overhaul of its ‘definition’ by the remaining publishers of this widely used benchmark.

Recognition of the unreliability of AWP (or of its continued availability) as a benchmark of real-world prices actually paid by pharmacies and other purchasers, including physicians, has precipitated the search for other reference prices for payment purposes. The uncertainty of AWP as a basis for payment for pharmaceuticals in the United States became an issue for all stakeholders on March 17, 2009, with the decision by U.S. District Court Judge Saris on the proposed settlement in the two national class action lawsuits against First Databank and McKesson. This decision resulted in the roll-back of the multiplier used to calculate AWP. The WAC multiplier of 1.25 (or greater than 1.20) was reduced to 1.20 for the 1,442 National Drug Code (NDC) numbers referenced in the lawsuit, effective September 26, 2009, under order of the court in acceptance of the proposed settlement. First Databank, an independent commercial publisher of drug pricing information, announced that it would discontinue publication of AWP no later than 2 years following implementation of the recalculated AWP— and has done so. Medi-Span made a similar announcement at the time, but ultimately reversed that decision, announcing that it will continue to publish AWP until there is a generally accepted alternative.² Truven Healthcare, publisher of *Redbook*, and Elsevier, publisher of *Gold Standard (ProspectoRx)* continue to publish AWP as of the publication date of this *Guide*.

While several independent publishers have proposed alternative pricing benchmarks, at the time of this publication, no comprehensive, transparent, and widely acceptable alternative to AWP has been identified.

Average Sales Price

As a result of the 2003 Medicare Prescription Drug, Improvement, and Modernization Act (MMA) (Public Law 108-173), ASP replaced AWP as the basis for payment for most drugs covered under Medicare’s medical benefit—Medicare Part B—as of January 1, 2005. Unlike AWP, ASP is based on manufacturer-reported actual selling price data and includes the majority of rebates, volume discounts, and other price concessions offered to all classes of trade (excluded from the calculation of ASP are all sales that are exempt from “best price” and sales at “nominal price” [see Glossary]).

Because ASP is a volume-weighted average, some providers are able to obtain pharmaceuticals below this average selling price, while others are able only to purchase the drugs at a price that is above the average. ASP prices are based on manufacturer-submitted data that is two quarters in arrears, and do not include subsequent pricing changes. In general, small physician offices and regional specialty pharmacies buy small quantities at the least favorable prices and are unable to purchase some drugs at prices at or below the ASP prices or ASP-based payment amounts. Generally, large physician groups and hospitals are able to negotiate the best discounts and price concessions and are better positioned under the ASP payment system.

From a payer perspective, ASP can also create misaligned incentives to dispense higher cost drugs due to a flat 6% mark-up in Medicare Part B (larger mark-ups are applied by some commercial health plans), when less expensive alternatives exist. Some commercial health plans have implemented a tiered mark-up on ASP, varying with compliance to health plan prescribing policies (for example, Blue Shield of California Professional fee Schedule. See: <https://www.blueshieldca.com/provider/claims/fee-schedules/home.sp>).

Average Manufacturer Price

Congress created Average Manufacturer Price (AMP) as part of the Omnibus Budget Reconciliation Act (OBRA 1990) for the purpose of calculating rebates to be paid by manufacturers to states for drugs dispensed to their Medicaid beneficiaries. AMP was defined as the price available to the retail class of trade and reflected discounts and other price concessions afforded those entities. The Deficit Reduction Act of 2005 (DRA) mandated that AMP instead of AWP be used for the calculation of the FUL.

Like ASP, AMP represents an effort by the federal government to step away from AWP to an alternate benchmark price. In 2003, the AMP approximated 79% of AWP for brand name drugs with no generic equivalents. The Congressional Budget Office (CBO) estimated that the acquisition cost to retail pharmacies averages approximately 4% above the AMP for brand name drugs without generic equivalents.³

In March 2010, the Patient Protection and Affordable Care Act (PPACA, PL 111-148) changed the definition of AMP, to represent the average price paid to the manufacturer by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer. PPACA excluded certain payments and rebates or discounts provided to certain providers and payers from calculation of AMP, including wholesaler customary prompt pay discounts, certain bona fide services fees, manufacturer reimbursement for unsalable returned goods, and payments, rebates or discounts related to entities that do not conduct business as a wholesaler or retail community pharmacy.

Federal Upper Limit

The Deficit Reduction Act of 2005 (DRA) mandated that AMP instead of AWP be used for the calculation of the federal upper limit (FUL), the maximum amount of pharmacy reimbursement for product costs for certain generic and multiple-source drugs that the federal government will recognize in calculating federal matching funds for payment to state Medicaid programs. That is, Federal Medicaid matching funds to states are limited to payments that do not exceed the FUL in the aggregate for multiple-source drugs, plus a dispensing fee set by each state. The FUL list is created and maintained by CMS for use by states in their Medicaid Pharmacy programs, but it is also in the public domain for use by any entity.

Effective October 1, 2010, PPACA revised the Social Security Act to require HHS to calculate the FUL as no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer price (AMP) for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. In a study published October 2012, the Office of Inspector General reported that FUL amounts based on published prices were more than four times total pharmacy acquisition costs; and that AMP-based FULs were 61% lower than published price-based FULs at the median.⁴

CMS has proposed that FUL be a unit price calculated for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, meaning A-rated in the FDA Orange Book.⁵ “Initially a FUL will not be published for any FUL group that does not contain at least three innovator and/or non-innovator drug products at the NDC-9 level, that are “A rated” with three monthly AMP prices with AMP units greater than zero reported and certified by manufacturers to calculate the weighted average of monthly AMPs.”⁶

CMS has issued draft AMP-based FUL reimbursement files for review and comment, for multiple source drugs, including

the draft methodology used to calculate the FULs.^{7,8} Because posted monthly AMP-based FULs fluctuated significantly month-to-month, CMS created an alternative methodology based on a rolling 3-month average of the monthly AMP-based FULs.⁹ However, the monthly and three month rolling average FUL files do not exactly match, because CMS does not have three months of data for all drugs, and because the older data may be less reflective of pharmacies’ current purchase price. As of publication of this *Guide*, these results are posted on the CMS website for review and comment.¹⁰ Until the draft is finalized, CMS is using the prior formula of 150% of the lowest published price as an “interim methodology” to calculate FULs.⁴

Best Price

Medicaid best price was created by OBRA 90 and took effect January 1, 1991 in the calculation of rebates that manufacturers are required to pay to the states and the federal government for sales of single-source and multiple-source branded products to Medicaid beneficiaries. According to a Congressional Budget Office (CBO) report published in June 2005, best price for brand-name drugs approximates 63% of AWP.

Maximum Allowable Cost or Maximum Reimbursement Amount

Maximum allowable cost (MAC), also referred to as maximum reimbursement amount (MRA) is typically a reimbursement limit per individual multiple-source pharmaceutical, strength and dosage form. MAC price lists are established by health plans and PBMs for private sector clients and by many states for multiple-source pharmaceuticals paid for by their Medicaid and other state-funded programs. Private sector MACs usually are considered confidential. While clearly defined in FUL for Medicaid, there is no standardized private sector definition, methodology, update timing or market application for MAC.

Medicaid generic drug cost containment in some states is built around MAC programs. Those state Medicaid programs create their own lists of maximum reimbursement prices for generic drugs. As a general rule, state MAC lists include more drugs and establish lower reimbursements than the FUL list because they are not bound by the FUL three-drug/three-supplier rule, nor by the FUL payment methodology. For a drug on the FUL list, the state MAC can be lower but not higher than the FUL.

National Average Retail Price and National Average Drug Acquisition Cost

State Medicaid programs currently reimburse pharmacies for covered outpatient drugs based, in part, on the estimated acquisition cost (EAC), the agency’s best estimate of the price generally and currently paid by providers for a drug marketed or

sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers. On February 2, 2012, in CMS-2345-P, CMS proposed replacement of EAC with estimated actual acquisition cost (AAC), and engaged (through competitive procurement) Myers & Stauffer (a private accounting firm) to provide state Medicaid agencies with acquisition costs and consumer purchase prices of covered outpatient drugs dispensed by pharmacies (not including specialty pharmacies), through a recurring pharmacy survey described in “Survey of Retail Prices: Payment and Utilization Rates and Performance Rankings”.

The survey objectives are to collect data for calculation of National Average Retail Price (NARP), a monthly pricing database of actual drug prices provided voluntarily by independent and chain pharmacies in the United States, including for cash paying customers, customers with commercial third party insurance, and Medicaid customers. Another survey objective, established by CMS but not mandated in PPACA, is to collect data on the purchase prices of all Medicaid covered outpatient drugs dispensed by independent community pharmacies and chain pharmacies, for calculation of the National Average Drug Acquisition Cost (NADAC). As with AMP-based FUL, CMS has posted draft NARP and NADAC reimbursement files for review and comment by the public.¹¹

Separately, some state Medicaid programs have implemented or are in the process of implementing an AAC-based reimbursement methodology. These states include Alabama, Oregon, Idaho, Iowa, Louisiana, California and New York.¹²

Public Health Service 340B Price

Public Health Service (PHS or 340B) price (referred to as a ‘340B ceiling price’) is the highest price that a ‘340B-covered entity’ could be charged, and is equal to the price that the state Medicaid agency would pay absent any supplemental discount or rebate. However, 340B pricing can be better than Medicaid pricing because sales do not include retail pharmacy markups and because 340B providers usually negotiate sub-ceiling prices.

340B ceiling prices for brand-name drugs were reported to average 51% of AWP. PPACA expanded the 340B program to include certain children’s hospitals, freestanding cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. PPACA exempted pharmaceutical manufacturers from having to provide discounts on orphan drugs to these newly eligible entities, as proposed, if the drugs are used to treat diseases for which they received orphan-drug designation.

■ ■ Payers and Payment Methods

Payment to providers for the drugs they administer or dispense varies depending on the payer and the site of care.

Medicare

Medicare’s payment for drugs depends on the treatment setting. Drugs provided in the hospital inpatient setting typically do not receive separate payment, but instead their costs are accounted for in the diagnosis related group (DRG)-based prospective payment made to the hospital. Similarly, drugs used in the hospital outpatient department for which the cost per day is \$80 or less (for CY 2013) are bundled into ambulatory payment classification (APC) reimbursement for the procedures with which they are used; there is no separate payment made for those drugs. For CY 2013, CMS will pay acquisition and pharmacy overhead cost for hospital outpatient separately payable drugs and biological without pass-through status at ASP plus 6%. Part B prescription drugs administered in the physician office or clinic are also paid at ASP plus 6%.

The Federal Government’s financial and budget issues have the potential to cause changes in reimbursement. For example, the Sequester of 2013 will result in reduction of Medicare Part B payment from ASP+6% to ASP+4% for claims on or after April 1st. However, as of the time of publication of this *Guide*, it is not possible to know if this change in reimbursement will be sustained or if there may be other changes in federal health services reimbursement. It is also impossible to know if these changes in federal reimbursement will influence or affect reimbursement by commercial entities that sometimes emulate government reimbursement methods.

For end stage renal dialysis, injectable and oral drugs with injectable equivalents administered in relationship to dialysis treatment are included in the Medicare per-dialysis prospective payment.¹⁴ The American Taxpayer Relief Act (H.R. 8), signed into law on January 1, 2013, included delay in addition to the prospective payment of orals-only drugs related to dialysis treatment until January 1, 2016 (previously these drugs had been scheduled for addition to the prospective payment on January 1, 2014).¹⁵

On January 1, 2006, as a result of passage of the MMA, Medicare began to pay for outpatient pharmaceuticals dispensed at the pharmacy under Part D. Part D benefits are provided through stand-alone prescription drug plans (PDPs) or Medicare Advantage prescription drug plans that are integrated with a medical plan (MA-PDs). These drug plans typically are offered by PBMs and commercial health plans. Subject to legislated mandates and to CMS guidelines and approval, each PDP and MA-PD sets its own premiums, benefit structures, drug

formularies, pharmacy networks, and terms of payment. Thus, unlike the other components of Medicare where a standard payment formula typically exists, drug payment to pharmacies and member cost-share vary by individual plan under Part D.

Part D plans and MA-PDs may negotiate discounts and/or rebates with drug manufacturers. In late 2012, it was proposed that Part D drug sales for dual eligible and low income beneficiaries, together representing approximately 56% of Part D enrolled patients, be made subject to Medicaid statutory drug rebates. However no such change has been implemented as of the publication date of this *Guide*.¹⁶

Medicaid

Currently, every state Medicaid program includes an outpatient prescription drug benefit (also called a “pharmacy benefit”). As of July 1, 2011, 74.2% of Medicaid enrollees nationwide were enrolled in managed care plans, including health insuring organizations, commercial managed care organizations, Medicaid-only managed care organizations, Primary Care Case Management, prepaid inpatient health plans, prepaid ambulatory health plans, programs for all-inclusive care for the elderly and others. However health insuring organizations, commercial managed care organizations and Medicaid-only managed care organizations represented only 47% of this enrollee pool.¹⁷

Under fee-for-service Medicaid, most states pay pharmacies directly for the drugs dispensed to Medicaid beneficiaries, using a rate based on AWP or WAC for brand drugs and maximum allowable cost (MAC, based on federal and state upper limits) for multiple-source brand and generic drugs. Several states have implemented average Actual Acquisition Cost (AAC)-based reimbursement as well.¹⁸ If the beneficiary is enrolled in a Medicaid managed care plan, the state may pay the Medicaid managed care plan to cover pharmacy benefits for beneficiaries, or the state may choose to “carve out” the pharmacy benefit and pay for it directly under fee-for-service administered by the state. Under managed Medicaid without carve-out, each MCO negotiates with drug manufacturers for rebates and discounts and manages its own drug formulary and network. Under carve-out, the state pays pharmacies for prescription drugs directly and manages a statewide formulary that may include a preferred drug list (PDL) and supplemental rebates as well as rebates mandated by federal statute. Beneficiaries who are eligible for both Medicaid and Medicare (“Medi/Medi” or “dual eligibles”) receive prescription drug benefits through the Medicare Part D outpatient drug benefit.

When pharmacy benefits are carved into Medicaid managed care contracts, CMS requires states to collect drug utilization data, for collection of statutory rebates from pharmaceutical manufacturers. However, in a study conducted in Q2 2011, the

OIG found that 10 of 22 states using the carve-in approach did not collect rebates.¹⁹

Every state Medicaid program, either directly or through managed Medicaid organizations, also pays for drugs that are utilized under the medical benefit (e.g., in the physician’s office and clinic). Drugs covered under the medical benefit are typically paid for differently than are drugs covered under the pharmacy benefit, using formulas that vary by state, that are based on AWP, WAC, or ASP. States are required to collect rebates for drugs administered in these settings also, but as of 2009, not all states were in compliance.²⁰

Private Purchasers

Compared with public payers, there is less transparency in the payment methods used by private payers to pay for prescription drugs. For example, private payers use MAC price lists for multiple-source drugs; however, prices contained in these MAC lists, the methodology by which these lists are constructed, the frequency with which they are updated, and network pharmacies at which they apply are not publicly disclosed. Similar to public payers, private payers use drug formularies to manage beneficiary prescription drug use and the cost of drugs paid for by the plan. Most formularies have copayment “tiers” that correspond to different levels of beneficiary cost sharing. The placement of drugs within copayment tiers is related to their relative safety, efficacy, and effectiveness as determined by health plan or PBM pharmacy and therapeutics (P & T) committees as well as their direct cost, including the price concessions that private payers can obtain from drug manufacturers.²¹ It has been suggested that P & T committees refocus to address value-based reimbursement and accountable care.²² Generic drugs are most commonly placed in the lowest formulary copayment tier, although some formularies list preferred generics on the lowest tier, and non-preferred generics on the second tier together with preferred brands. Private payers negotiate drug payment rates with pharmacy providers; historically, these rates have been based on AWP or WAC, and include MAC pricing for most generic drugs.

As in Medicare DRGs, private payers prefer to bundle payment for prescription drugs in DRG-based payments or in per-diem rates for inpatient hospital, while hospital outpatient drugs are more commonly paid for separately if they exceed a specified cost threshold. Drugs administered in physician offices and clinics are usually paid separately based on AWP, WAC, or ASP.

Pilot programs are underway in several commercial settings to evaluate bundled payment mechanisms. A RAND Evidence-based Practice Center study published in August 2012 by the Agency for Healthcare Research and Quality concluded in part: “There is weak but consistent evidence that bundled payment programs have been effective in cost containment without major effects on

quality.”²³ Private sector initiatives include, for example, United Healthcare’s bundled payment pilot study in oncology.²⁴

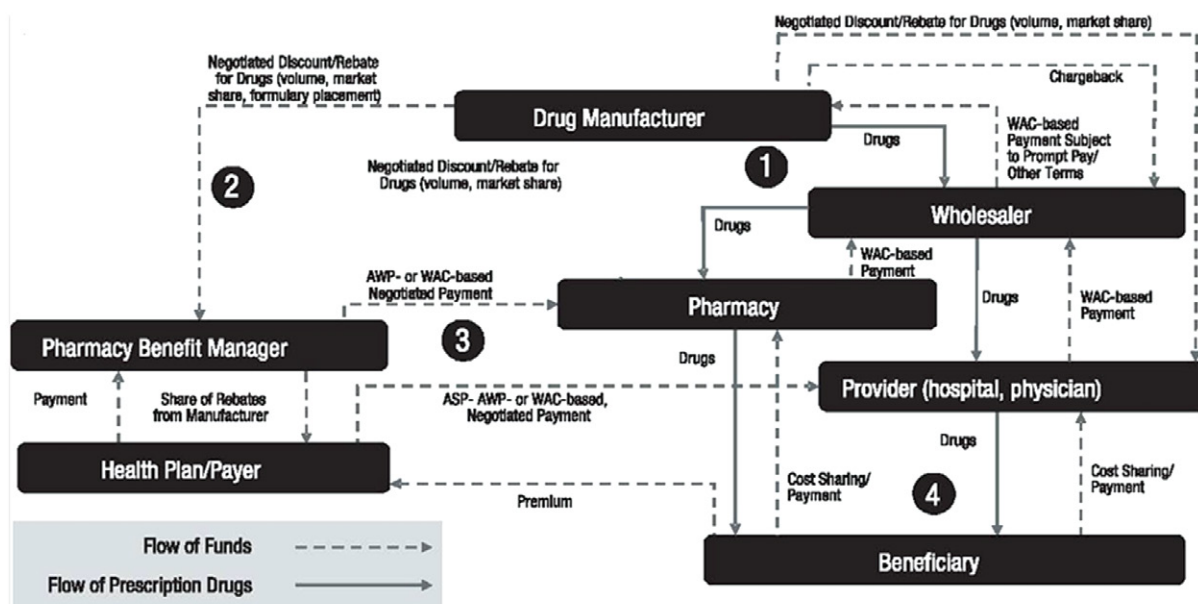
■ ■ How Products, Services, and Payments Flow Through Channels of Distribution (See Exhibit 1)

Any discussion of drug payment should consider the impact of channel of pharmaceutical distribution (e.g., hospital, physician, pharmacy) on both payment method and level.

1. The majority of drug manufacturers ship drugs directly to drug wholesalers or distributors, who then distribute the drugs to their end customers. Manufacturers enter into various forms of contracting arrangements, including discounts and rebates, with all of the entities within the pharmaceutical supply chain. Manufacturers typically offer different contracting arrangements, depending on customers’ channel of distribution or class of trade, which may be administered by wholesalers or distributors or directly with the manufacturers.
2. Health plans and PBMs also negotiate with manufacturers for discounts and rebates, primarily for single-source branded pharmaceuticals in competitive therapeutic categories purchased for the individuals enrolled in their plans or under their management, based on volume, market share, and formulary placement.

3. Pharmacies receive payment from the health plan or PBM for the drugs dispensed to the plan members based on a reimbursement formula agreed to by the payer (or agent) and pharmacy. Physicians and other providers also negotiate with health plans for payments for the drugs they administer directly to beneficiaries. Drug payment may be bundled in some channels (e.g., DRGs for hospital inpatient and, depending on circumstances, APCs for hospital outpatient), or in other channels (e.g., pharmacy and physician office) drugs may be paid on the basis of individual prescriptions dispensed or administered.
4. At the pharmacy counter or other point of sale, beneficiaries with health insurance that includes prescription benefit coverage will typically pay a cost-share to the pharmacy for the prescription drug. The cost-sharing type (e.g., copayment or coinsurance) and amount are set by the terms of that health plan member’s benefit design. If the pharmacy plan is administered by a PBM, the PBM then bills the member’s health plan or other payer an amount based on the payment formula stipulated in its provider service agreement, minus the beneficiary cost-share amount collected by the pharmacy. Individuals without health insurance or other coverage for the purchase of their prescription drugs or without the assistance of negotiated pricing through a “discount card” program must pay the pharmacy’s or other provider’s “usual and customary” (U&C) price to obtain their drugs.

EXHIBIT 1. DRUG DISTRIBUTION MODEL



Recent Pharmaceutical Payment Milestones

The timeline (Table 1) summarizes recent events affecting payment for prescription drugs and provides hyperlinks to obtain further information.

Disclosures

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TABLE 1. PHARMACEUTICAL PAYMENT MILESTONES: 2005–2013

Date	Description of Milestone	Key	References
January 1, 2005	Initiation of Average Sales Price for Medicare Part B medications, as a result of the 2003 Medicare Prescription Drug, Improvement, and Modernization Act (Public Law 108- 173).	CMS’s effort to establish a new payment benchmark for prescriptions administered in physician office, clinic and hospital outpatient settings.	http://www.gpo.gov/fdsys/pkg/PLAW-108publ173/pdf/PLAW-108publ173.pdf
January 1, 2006	Initiation of Medicare Part D, administered by stand-alone PDPs and by MA-PDs with prescription drugs and services delivered primarily by community pharmacies.	Competitive delivery model without centralized drug pricing, mandatory manufacturer rebates or community pharmacy reimbursement guidelines.	Medicare Part D Benefit Designs and Formularies 2006-2009. J Hoadley, for MedPAC. 12/5/08 http://www.medpac.gov/transcripts/MedPAC%20Formulary%20Presentation%20-%20Hoadley%2012-05-08%20revised.pdf
February 8, 2006	Deficit Reduction Act of 2005 establishes AMP as basis of Medicaid FUL calculation, and requires AMP to be publicly disclosed.	CMS’s effort to establish a new payment benchmark for prescriptions dispensed through pharmacy channels.	Deficit Reduction Act of 2005: Implications for Medicaid. 2/06. Kaiser Commission on Medicaid and the Uninsured. http://www.kff.org/medicaid/upload/7465.pdf
October 6, 2006	<i>Wall Street Journal</i> article reporting on litigation revealed for the first time that First Databank took action in 2002 to increase the markup of AWP from WAC for certain brand-name drugs.	First Databank increased the markup of WAC to determine AWP for a large number of drugs in 2002 from 1.20 to 1.25. AWP was not based on actual surveys of drug wholesaler prices.	Martinez B. How quiet moves by a publisher sway billions in drug spending. <i>Wall Street J.</i> October 6, 2006:A1. Available at: http://www.dc37.net/news/newsreleases/2006/drugpricing_WallStJ.pdf
November 14, 2006	U.S. District Court for the District of Massachusetts, Judge P. Saris, granted preliminary approval to a settlement in class action re AWP with First Databank	Public disclosure of disconnect between AWP and actual market prices.	Proposed Settlement by Judge Saris in CIVIL ACTION NO. 05-11148-PBS; New England Carpenters Benefit Fund et al. vs. First Databank-McKesson. Available at: http://www.prescriptionaccess.org/docs/FDB-prelim-approval-order2.pdf

Continues.

TABLE 1. PHARMACEUTICAL PAYMENT MILESTONES: 2005–2013 (Continued)

Date	Description of Milestone	Key	References
July 6, 2007	Deficit Reduction Act of 2005 definition of “retail pharmacy class of trade” for AMP calculation purposes, and of class of trade to be included in the AMP calculation.	Retail pharmacy class of trade means any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public. Sales, rebates, discounts, or other price concessions included in AMP. Includes several non-retail pharmacy channels (see references).	Medicaid Drug Pricing Regulation. CMS Fact Sheet. 7/6/07. http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=11424 and Section 447.504, Determination of AMP. http://www.gpo.gov/fdsys/pkg/CFR-2008-title42-vol4/pdf/CFR-2008-title42-vol4-sec447-504.pdf and Retail Pharmacy class of trade, <i>Federal Register</i> v72 #136, 7/17/07. http://www.gpo.gov/fdsys/pkg/FR-2007-07-17/html/07-3356.htm
November 1, 2007	Judgments against two major brand-name drug manufacturers for “grossly inflating” the AWP of certain expensive physician-administered drugs (PADs).	Public disclosure of disconnect between AWP and actual market prices with respect to particular products; preceded by about 7 years of allegations and settlements between several pharmaceutical manufacturers and state and federal prosecutors over inflating the “spread” between AWP and actual acquisition cost for physicians.	Memorandum and order by Judge Saris in: Re MDL 1456 and Civil Action No. 01-12257-PBS. Available at: http://wexlerwallace.us/files/00079404.pdf
July 2008	Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).	With a federal court injunction, results in delay of (a) expansion of the number of drugs subject to the FUL amounts, (b) change in the basis for the calculation of FUL amounts to AMP, and (c) requirement that CMS share AMP data with states.	http://www.gpo.gov/fdsys/pkg/PLAW-110publ275/pdf/PLAW-110publ275.pdf
December 31, 2008	CMS’s Medicare Part B drug Competitive Acquisition Program (CAP) postponed as of December 31, 2008.	Postponed because of contractual issues with successful bidder. No official notice regarding if or when program may be restarted.	http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/CompetitiveAcquisforBios/index.html

Continues.

TABLE 1. PHARMACEUTICAL PAYMENT MILESTONES: 2005–2013 (Continued)

Date	Description of Milestone	Key	References
January 2009	Hospital outpatient settings: Payment for non-pass-through drugs and biologicals in CY 2009 is made at a single rate of ASP + 4%, which includes payment for both the acquisition cost and pharmacy overhead costs associated with the drug or biological. For pass-through drugs and biologicals in CY 2009, a single payment of ASP + 6% is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items.	For CY 2009, separate drug payment in hospital outpatient settings reduced to ASP + 4% for non-pass-through drugs and biologicals. For CY 2009, pass-through drug payment continues at ASP + 6%.	http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1702CP.pdf
January 2009	The American Recovery and Reinvestment Act of 2009 provides \$1.1 billion funding for comparative effectiveness (CE) research through the Agency for Healthcare Research and Quality (AHRQ) and the National Institutes of Health (NIH), and establishes the Federal Coordinating Council for Comparative Effectiveness.	Objective is to increase research that compares treatment modalities. The hope is that availability of CE research results will help care givers make best possible therapeutic choices. Council is precluded from making coverage or reimbursement decisions.	Comparative Effectiveness. J Holzer, G Anderson. <i>Health Policy Monitor</i> . 2009. Available at: http://hpm.org/en/Surveys/Johns_Hopkins_Bloomberg_School_of_Publ_H_USA/13/Comparative_Effectiveness_Research.html
February 2009	OIG release of comparison of community pharmacy reimbursement amounts for Medicare Part D plans versus Medicaid in the second half of 2009 for 40 single-source drugs and 39 multiple-source drugs with high expenditures.	Analysis of “average unit reimbursement amount” including dispensing fee with ingredient cost. Median 0.6% lower Part D reimbursement for single-source brand drugs. Medicaid reimbursement exceeded Medicare Part D reimbursement by 10% or more for 28 of 39 multiple-source drugs and was 17% higher at the median for the 39 multiple-source drugs.	DHHS Office of Inspector General. Comparing pharmacy reimbursement: Medicare Part D to Medicaid. Report no. OEI-03-07-00350. February 2009. Available at: https://oig.hhs.gov/oei/reports/oei-03-07-00350.pdf

Continues.

TABLE 1. PHARMACEUTICAL PAYMENT MILESTONES: 2005–2013 (Continued)

Date	Description of Milestone	Key	References
March 17, 2009	U.S. District Court judge approves settlement between drug price clearinghouses Medi-Span and First Databank (with drug wholesaler McKesson) and plaintiff health plans alleging “fraudulent increase of AWP.”	Adjust AWP for approximately 1,400 NDCs to smaller gross margin (1.20xWAC rather than 1.25xWAC), effective September 26, 2009. Establish a reasonably accessible data repository of discoverable material regarding First Databank drug price reporting practices. First Databank independent of this court decision commits to discontinuation of publication of AWP within 2 years, on or before September 26, 2011.	U.S. District Court. District of Massachusetts. <i>New England Carpenters Health Benefits Fund, et al. vs. First Databank, Inc., and McKesson Corporation; and District Council 37 Health and Security Plan vs. Medi-Span</i> . Civil Action No. 05-11148-PBS and Civil Action No. 07-10988-PBS. Available at: http://pacer.mad.uscourts.gov/dc/cgi-bin/recentops.pl?filename=saris/pdf
July 13, 2009	“Proposed Rule: Medicare Program: Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010” [CMS-1413-P], CMS proposed several changes to the Medicare drug Competitive Acquisition Program (CAP).	The Medicare Competitive Acquisition Program for Part B drugs has not been reinstated as of the 2013 publication date of this <i>Guide</i> .	http://www.gpo.gov/fdsys/pkg/FR-2009-07-13/pdf/E9-15835.pdf
September 26, 2009	U.S. District Court judge issues final order and judgment in case of Medi-Span and First Databank cases.	Effective date of order. (see March 17, 2009 above)	See March 17, 2009, above
October 1, 2009	No longer blocked as of this date: (a) Medicaid implementation of AMP as FUL payment benchmark, and (b) CMS publication of AMP data on its Web site.	Temporary suspension of public availability of AMP. Notwithstanding clause (v) of section 1927(b) (3)(D) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)), the Secretary of Health and Human Services shall not, prior to October 1, 2009, make publicly available any AMP disclosed to the Secretary. (MIPPA, Public Law 110-275, 7/15/08).	http://www.gpo.gov/fdsys/pkg/PLAW-110publ275/html/PLAW-110publ275.htm
By September 26, 2011	First Databank and Medi-Span voluntarily cease publication of AWP no later than this date.	Publication of other manufacturer-provided suggested pricing benchmarks, such as direct price and wholesale acquisition cost, are not affected.	http://publications.milliman.com/periodicals/health-perspectives/pdfs/health-perspectives-august-2009.pdf

Continues.

TABLE 1. PHARMACEUTICAL PAYMENT MILESTONES: 2005–2013 (Continued)

Date	Description of Milestone	Key	References
October 1, 2010	The Affordable Care Act modified the previous statutory provisions that establish a Federal Upper Limit (FUL) on multiple source drugs. Effective October 1, 2010, the Social Security Act was revised to require that the Secretary calculate FULs as no less than 175 percent of the weighted average (determined on the basis of manufacturer utilization) of the most recently reported monthly average manufacturer prices (AMP) for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis.	CMS posts ACA FUL and weighted average AMP to its website To minimize month-to-month fluctuations, CMS posts 3 month rolling average ACA FUL to its website.	http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/MethodologyGuide-AMP-BasedFULnew.pdf and http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits.html and http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/December-5-2012webinarpresentation.pdf
September 28, 2011	First Databank discontinues publication of AWP. Medi-Span continues publication of AWP.	Only First Databank discontinues publication of AWP	http://www.fdbhealth.com/policies/drug-pricing-policy/ and http://www.medisp.com/common/pdf/wkh_AWP_policy.pdf and http://www.medisp.com/Pricing-Policy-Update-2.aspx
June 2012	CMS publishes “Part I: Draft Methodology for Estimating National Average Retail Prices (NARP) for Medicaid Covered Outpatient Drugs”	CMS contracts with Myers & Stauffer to prepare a monthly report of the national average retail price (NARP) of Medicaid covered outpatient drugs by National Drug Code (NDC). Myers & Stauffer will also report the average drug price paid by cash, Medicaid, and third party insurance customers. NARP files posted to CMS website on monthly basis.	http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/NARPDraftMethodology.pdf and http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html
May 2012	CMS publishes “Part II: Draft Methodology for Calculating the National Average Drug Acquisition Cost (NADAC)”	See note regarding Myers & Stauffer for June 2012 NADAC posted to CMS website on weekly basis.	http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/NADACDraftMethodology.pdf and http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html
March 2013	President issues Sequestration order for Fiscal 2013, pursuant to Section 251A of the Balanced Budget & Emergency Deficit Control Act, as amended.	Sequestration interpreted to impact reimbursement for Medicare Part B prescription drugs, reducing reimbursement to ASP+4% for claims submitted on or after April 1, 2013.	http://www.gpo.gov/fdsys/pkg/FR-2013-03-06/html/2013-05397.htm

I. Introduction

Prescription pharmaceuticals are unlike any other segment of the health care marketplace in the complexity and variation of how the finished goods are priced to intermediate and final purchasers, and ultimately how much is paid when the product is dispensed or administered to the patient. In response to a growing need by all stakeholders²⁵ for detailed information on this complex topic, the Academy of Managed Care Pharmacy (AMCP) has produced this 2013 update to the *AMCP Guide to Pharmaceutical Payment Methods*.¹

For many years and until recently, pharmaceutical prices increased at rates that far exceeded other segments of health care and propelled increases in pharmaceutical spending.²⁶ In the private sector, the 2012 Milliman Medical Index suggests that the pharmacy costs of preferred provider organization (PPO) health plans have moderated somewhat in recent years (see Exhibit I-1).

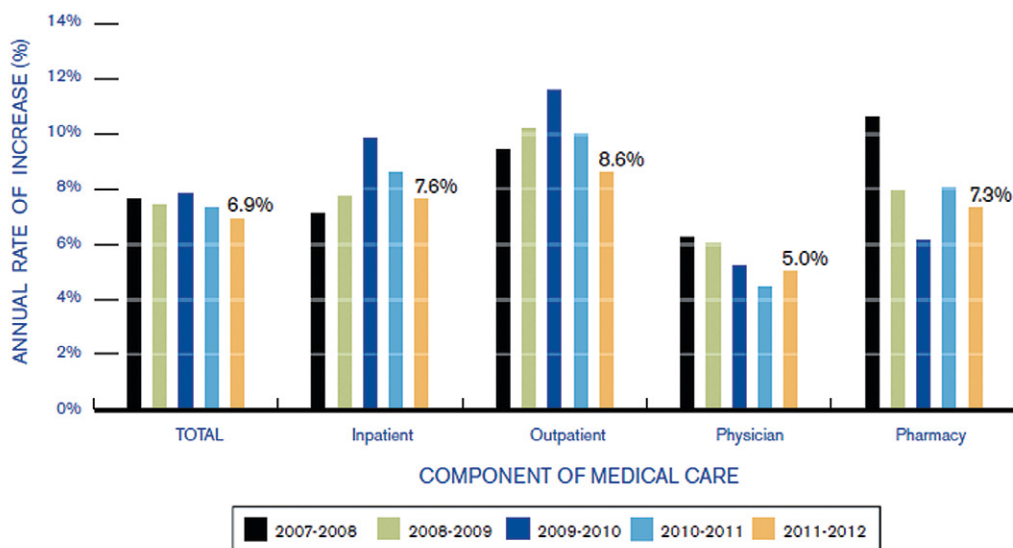
IMS reports that while nominal spending on prescription drugs increased by 3.7% in 2011, real per capita spending that

year increased by 0.5% after adjusting for GDP and population growth. IMS projected that the pharmaceutical market would recover with the economy in future years, but “an unprecedented level of potential patent expirations in 2011 and 2012 will curb sales growth.”²⁸ Another concern is the increasing cost of new pharmaceutical treatments. The following chart shows monthly and median costs of cancer drugs at the time of approval by the U.S. Food and Drug Administration (FDA), from 1965 through 2008 (see Exhibit I-2).²⁹

The federal government has responded to escalated spending on pharmaceuticals by becoming increasingly involved in pricing and payment dynamics. The interest of Congress in pharmaceutical payment, supported by research and investigations by its committees and agencies (e.g., Government Accountability Office [GAO], Congressional Budget Office [CBO], MedPAC, Congressional Research Service, and the House Committee on Energy and Commerce) and federal executive agencies, has led to fundamental changes in the methods by which federal programs pay for prescription pharmaceuticals.

EXHIBIT I-1. MILLIMAN MEDICAL INDEX ANNUAL RATE OF INCREASE IN COSTS BY COMPONENT OF MEDICAL CARE^a

MMI ANNUAL RATE OF INCREASE IN COSTS BY COMPONENT OF MEDICAL CARE

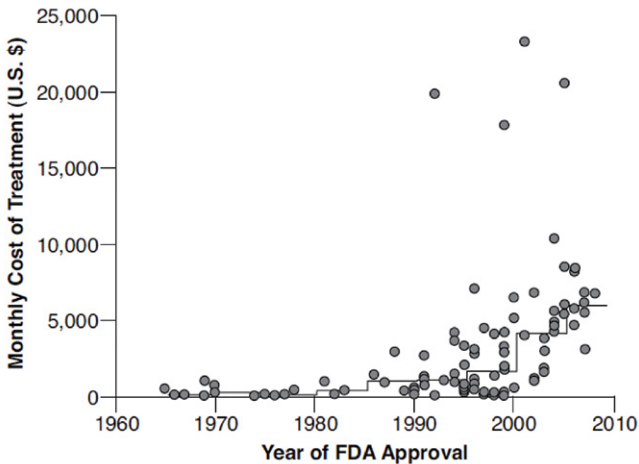


^a Average medical spending for typical American family of 4 covered by an employer-sponsored PPO program.

Source: 2012 Milliman Medical Index. May 2012.²⁷

I. INTRODUCTION

EXHIBIT 1-2. MONTHLY AND MEDIAN COSTS OF CANCER DRUGS AT THE TIME OF APPROVAL BY THE FDA, 1965–2008



Shown are costs for 1 month of cancer treatment for a person who weighs 70 kg or has a body-surface area of 1.7 m². The line indicates median prices during a 5-year period. Prices have been adjusted to 2007 dollars and reflect the total price for the drug at the time of approval, including both the amount of Medicare reimbursement and the amount paid by the patient or by a secondary payer. (For details about the costs of individual drugs, see the Supplementary Appendix, available with the full text of this article at NEJM.org)

Reproduced with permission: Bach, PB. Limits on Medicare's ability to control rising spending on cancer drugs. *N Engl J Med.* 2009;360(6):627. Available at <http://www.nejm.org/doi/full/10.1056/NEJMhpr0807774>. Accessed January 16, 2013.

The Patient Protection and Affordable Care Act, as amended by the Reconciliation Act, both enacted in 2010, significantly impact payment of prescription pharmaceuticals.³⁰ *Minimum Medicaid drug rebates:* Increased to 23.1% (from 15.1%) of the Average Manufacturer Price (AMP) for single source drugs, and 13% (from 11%) of Average Manufacturer Price for non-innovator multiple source drugs. For clotting factors and drugs approved exclusively for pediatric indications, the rebate is 17.1%.

- *Line extension rebate:* For line extensions of oral solid dosage forms of single source or innovator multiple source drugs (e.g., new formulations such as extended release), an additional Medicaid rebate percentage equal to the greater of (a) the additional rebate percentage calculated under

prior law for the original drug product (i.e., faster increase in product AMP than the consumer price index, measured since the time of the product's launch) or (b) the additional rebate percentage calculated for any strength of the original drug product.

- *Medicaid managed care:* Drug utilization to Medicaid patients enrolled in managed care organizations become subject to drug rebates.
- *Federal Upper Reimbursement Limit (FUL):* The formula for calculating the FUL was changed, as were the definitions of AMP and of multiple source drug. The new FUL formula is no less than 175% of the weighted average (based on utilization) of the most recently reported monthly AMP. AMP was redefined as the average price paid, less certain exclusions, to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies, and by retail community pharmacies purchasing directly from manufacturers. Only weighted average AMP, not individual manufacturer AMP, may be publicly disclosed.
- *Public Health Service 340B discounts:* 340B program eligibility (except for FDA-designated orphan drugs) is extended to additional covered entities, including Medicare PPS-exempt children's hospitals, cancer hospitals that meet disproportionate share eligibility criteria, critical access hospitals, and rural referral centers or sole community hospitals with disproportionate share adjustments of greater than or equal to 8%. 340B covered entities may not obtain covered outpatient drugs from Group Purchasing Organizations.
- *Biosimilar biological products:* Medicare Part B payment for biosimilar biologics is set at Average Sales Price plus 6% of the reference or brand biological product.

This *Guide* offers a comprehensive overview as well as a selected focus on details concerning the most important changes to pharmaceutical payment. The four main subject areas are:

- Payment Benchmarks
- Payers and Payment Methods
- How Products, Services, and Payments Flow Through Channels of Distribution
- Issues and Implications for Stakeholders

AMCP intends this *Guide* to be an unbiased presentation of information, issues, and implications. The *Guide* is neither an expression of AMCP policy, nor does it intend to advocate any position on behalf of AMCP or its members on any issue contained herein.

II. Payment Benchmarks

Over the years, government, providers, manufacturers, and data publishers have created a wide range of benchmarks and price references that they and their customers continue to use for charges and payment. Average wholesale price (AWP) has historically been the most widely used benchmark, followed by WAC.

Activity to replace AWP as a benchmark came to a head in 2006-2007 as it became increasingly evident that AWP bore little resemblance to the actual price paid by the pharmacy.

Increasingly referred to as “Ain’t What’s Paid,” the federal government substituted average sales price (ASP) for AWP for reimbursement of most Medicare Part B drugs. In Fall 2006, the discovery process in a national class action lawsuit revealed that (a) there was no “average” in AWP, and (b) the primary source of AWP had unilaterally adopted a common margin of 20% (otherwise known as markup of 1.25) between AWP and wholesale acquisition cost (WAC) for nearly all brand drugs.^{31,32} Through the discovery process in the litigation, it was learned that “beginning in 2001, First Databank (FDB) and McKesson reached a secret agreement to raise the margin between WAC and AWP from its standard 20% to 25% for more than 400 drugs. McKesson communicated their new 25% WAC to AWP markups to FDB, which then published AWP’s with the new markups.”³³

Despite announcements by FDB and other publishers that AWP would be replaced, in 2013 it continues to be routinely used by payers. The industry has yet to converge on an alternative benchmark satisfying all stakeholders.

The following section provides a description of AWP and all other commonly used benchmarks.

■ ■ Benchmarks

Average Wholesale Price

Created in the 1960s, AWP was the first generally accepted standard pricing benchmark for payment of prescriptions dispensed through retail channels and of pharmaceuticals administered in the medical office by the majority of payers because this information was readily available from several suppliers.^{34, 35} At that time, AWP was considered to be an appropriate estimate of the actual acquisition cost (AAC).

In recent years, AWP has been referred to as “essentially a sticker price and does not directly correspond to any actual market transaction.”³⁶ It is not an average of prices charged by wholesalers to providers, but, for branded drugs, is rather a price calculated by publishing companies on the basis of pricing data

provided by drug manufacturers.³⁷ It is widely understood that pharmacies and other providers have been able to purchase brand pharmaceuticals at net prices below AWP, and pharmacy reimbursement rates reflect some of the difference between AAC and AWP. For the past 25 years or more, price competition has resulted in ever larger AWP discounts in provider service agreements between pharmacy providers and payers (e.g., health plans and PBMs). While the comparison is confounded by a change in markup percentage from WAC to AWP (as discussed in the next paragraph), the average reimbursement rate for community pharmacies for brand drugs declined from AWP minus 13.2% plus a dispensing fee of \$2.25 per prescription in 1998 to AWP minus 16.1% plus a dispensing fee of \$1.68 in 2012, and reimbursement to mail order pharmacies for brand drugs declined from AWP minus 17.1% in 1998 to AWP minus 23.1% in 2012.³⁸ With the advent of ASP as a benchmark for pharmaceuticals payable under Part B, Medicare’s use of AWP ended on January 1, 2005, for all but a handful of pharmaceuticals.³⁹

A final Memorandum and Order was issued on March 17, 2009, in the national class actions against First Databank, McKesson, and Medi-Span in U.S. District Court for the District of Massachusetts, which requires First Databank and Medi-Span to “roll back from 1.25 to 1.20 the wholesale average cost to AWP markup for all of the 1,442 NDCs affected by the fraudulent scheme” no earlier than six months following entry of the final judgment.³³ In response to this ruling, First Databank reiterated its intention to apply a 1.20 factor in calculating AWP’s for all other NDCs whose AWP’s were previously set based on a factor greater than 1.20, and to discontinue publication of AWP no later than two years following implementation of these changes—which it did. Medi-Span made a similar announcement, but decided to continue publication of AWP pending availability of a suitable replacement benchmark. Truven Health Analytics, publisher of *Redbook*; and Elsevier, publisher of *Gold Standard (ProspectoRx)*, continue to publish AWP as of the publication date of this *Guide*.^{40, 41}

Subsequent to the reduction of markup from WAC to AWP, third-party pharmacy reimbursement contract AWP discounts were adjusted to maintain the relative economics of all stakeholders.⁴²

The following table shows individual publishers’ approach to benchmark pricing, including determination of AWP, on the basis of WAC (Wholesale Acquisition Cost), DP (Direct price) or SWP (Suggested Wholesale Price):

II. PAYMENT BENCHMARKS

Source	AWP Determination Methodology
First Databank	Discontinued publication of AWP on September 28, 2011. WAC, DP and/or SWP are reported as supplied by the manufacturer.
Medi-Span	Multiple of WAC (using factor of 1.2) to calculate reported AWP. If SWP is supplied by manufacturer, it is instead used as AWP.
Gold Standard	Two versions: multiple of WAC (using factor of 1.2 or 1.25) used to calculate reported AWP. If SWP is supplied by manufacturer, it is instead used as AWP.
Red Book	Multiple of WAC (using factor of 1.2) to calculate reported AWP. If SWP is supplied by manufacturer, it is instead used as AWP.

Wholesale Acquisition Cost

Wholesale acquisition cost (WAC) is the manufacturer’s reported list price for a prescription pharmaceutical for sale to wholesalers.³⁴ Each manufacturer establishes its own WAC by using its own formula. Price-reporting services, such as First Databank and Medi-Span, publish WAC prices supplied to them by manufacturers in their pharmaceutical information databases. Pharmaceutical contracts between manufacturers and private payers typically use AWP or WAC as the reference price.⁴³

The terms *list price*, *catalog price*, *wholesale net price*, *book price*, and *direct price* are used by some manufacturers as synonyms for WAC. Almost all single-source pharmaceuticals have a WAC price, but many generic pharmaceuticals, repackaged pharmaceuticals, or “house brands” do not because there is no legal requirement to report a WAC. Pharmaceuticals for which no WAC is reported may have a suggested wholesale price (SWP).

Like AWP, WAC is a suggested price that often does not represent what a wholesaler or end-provider actually pays for the pharmaceutical, because WAC does not include manufacturer incentives such as rebates, volume purchase agreements, and prompt-payment discounts. However, unlike AWP, WAC is statutorily defined in the U.S. Code:

The term “wholesale acquisition cost” means, with respect to a pharmaceutical or biological, the manufacturer’s list price for the pharmaceutical or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of pharmaceutical or biological pricing data.

WAC is a lower price than AWP because it is applied earlier in the distribution process. Some Medicaid programs use WAC as an alternative to AWP in their branded drug reimbursement formulas. Pharmaceutical benchmark reporting services may show the relationship of AWP and WAC in a constant ratio for branded products for each manufacturer (for example a constant ratio of 1.20 or 1.25).⁴¹ Because of the proportionate relationship between WAC and AWP for branded products, entities that establish the WAC effectively establish the published AWP and thus impact payer reimbursement in AWP-based payment systems that use published AWP data. In the private sector, WAC is often the basis of manufacturer rebate calculations.⁴⁵

Average Sales Price

Most drugs covered by Medicare Part B, including physician-administered infusions and injections and drugs administered in the hospital outpatient setting, are reimbursed at 106% of ASP. However, the Federal Government’s financial and budget issues have the potential to cause changes in reimbursement. For example, the Sequester of 2013 will result in reduction of Medicare Part B payment from ASP+6% to ASP+4% for claims on or after April 1st. However, as of the time of publication of this *Guide*, it is not possible to know if this change in reimbursement will be sustained or if there may be other changes in federal health services reimbursement. It is also impossible to know if these changes in federal reimbursement will influence or affect reimbursement by commercial entities.

ASP is based on the manufacturer’s actual selling price, which includes almost all forms of rebates and discounts reported to the federal government’s Centers for Medicare & Medicaid Services (CMS).

As defined by law, an ASP is a manufacturer’s sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions, such as volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program. Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of “best price” in Medicaid’s drug rebate program.⁴⁶

Following is the formula used by CMS beginning April 1, 2008, to calculate volume-weighted ASP:⁴⁶

$$\text{Volume-Weighted ASP for Dosage Amount of HCPCS Code} = \frac{\text{Sum of (ASP for NDC * Number of NDCs Sold)}}{\text{Sum of (Number of NDCs Sold * Number of Billing Units in NDC)}}$$

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There is a lag of two calendar quarters between the time when sales reflected in the ASP occur and the time when these sales are reported to CMS for ASP calculation and posting. The change in average sales price, which could be the result of loss of a brand's patent protection and market entry of generic competitors, or the result of a price increase, is thus not immediately reflected in the posted ASP. As a consequence, ASP-based reimbursement may be either too high or too low, until manufacturer-submitted data to CMS reflect this change in net market price. If too low, this may pose a short-term access barrier, because providers may be unwilling to accept reimbursement of less than drug's cost. If too high, this may yield a short-term windfall for providers.

For example: The innovator brand of irinotecan lost patent protection in late February 2008, and by the following month, generic versions accounted for 86% of sales with an average price of \$40.66. But during March, the innovator brand's average price remained almost three times higher than the generic, and the Q1 2008 Payment Amount (ASP + 6%) was \$126.31. The impact of generic price and volume only became apparent in Q4 2008 ASPs.⁴⁷

ASP has proven to be substantially lower than AWP, the former benchmark for Part B reimbursement. In a 2005 study, the Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS) found that, in the aggregate for all pharmaceuticals reviewed, "ASP is 49% lower than AWP at the median."⁴⁸

The Medicare Payment Advisory Commission (MedPAC) found that, from 2004 to 2005 when the payment rate changed to 106% of ASP, total claims volume and charges for each medical specialty reviewed (including pharmaceuticals, pharmaceutical administration, evaluation and management visits, tests, and other procedures) increased, but spending on pharmaceuticals decreased. The decline in expenditures for pharmaceuticals ranged from 1% for rheumatology to 52% for urology. Overall, total Part B pharmaceutical spending (considering price and volume changes) fell from \$10.9 billion in 2004 to \$10.1 billion in 2005.⁴⁹ By 2010, total Part B pharmaceutical spending had increased to \$11.5 billion.⁵⁰

Impact on Provider Practices. ASP is a volume-weighted average.⁴⁶ A provider whose acquisition cost is above the median will be adversely affected, while providers below the median will benefit. In the MedPAC study noted above,⁴⁹ most physicians reported that they were able to purchase most of their oncology pharmaceutical agents at the Medicare payment level. However, all physicians reported slim pharmaceutical profit margins, and reported that some products cannot be purchased at the payment rate. More recently, physicians report that some multiple source injectable drugs are in short supply or are unavailable.⁵¹ Many

physicians also reported that they have increased efficiencies in their practices in response to lower pharmaceutical payments.⁵²

One concern with ASP-based reimbursement is that it may undermine manufacturers' incentives to compete on price for single-source, therapeutically equivalent products. ASP also may discourage use of less expensive multiple-source products when a therapeutically equivalent brand is available at a higher ASP. Given the same 6% markup on all products regardless of underlying cost, the product with the highest dollar ASP provides the highest provider margin in dollars. To address this concern, some commercial health plans have implemented a tiered markup on ASP, varying with compliance to health plan prescribing policies (for example, Blue Shield of California Professional fee Schedule. See: <https://www.blueshieldca.com/provider/claims/fee-schedules/home.sp>).

ASP values are publicly available on the federal government's Centers for Medicare & Medicaid Services (CMS) Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>. Because it is readily available and updated quarterly, private payers are able to use ASP for payment of medical benefit drugs. Uptake of the ASP benchmark by commercial sector has been slow but steady. Survey data from approximately 60 payers together representing 153 million lives showed that, by the summer of 2011, about 57% of covered lives were subject to ASP-based reimbursement for specialty therapies, 27% were subject to AWP-based reimbursement, and the remainder were subject to variable fee schedule reimbursement.⁵³

Average Manufacturer Price

AMP was created in the early 1990s following enactment of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) as the basis for calculation of manufacturer rebates on outpatient pharmaceuticals dispensed to Medicaid beneficiaries. OBRA 90 required that pharmaceutical manufacturers enter into rebate agreements with CMS and pay quarterly rebates to the states to obtain Medicaid coverage and payment. The statutorily mandated rebate amounts are calculated based on the AMP, defined as follows (in this *Guide*, referred to as the 'standard AMP'):⁵

Average Manufacturer Price (AMP) means, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA)), the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.

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Like ASP, average manufacturer price (AMP) represents an effort by the federal government to step away from AWP to an alternate benchmark price. However AMP is unlike ASP in that, as required by PPACA, only weighted average AMP is posted to the CMS website, as a component of the draft AMP-based FUL

tables, at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits.html>.

In 2003, the AMP approximated 79% of AWP for brand name drugs with no generic equivalents. The Congressional

EXHIBIT II-1. COMPONENTS OF STANDARD AMP CALCULATION

Included Sales/Discounts	Excluded Sales/Discounts
Sales to wholesalers for drugs distributed to retail community pharmacies	Customary prompt pay discounts to wholesalers
Sales to other manufacturers who act as wholesalers for drugs distributed to retail community pharmacies.	Bona fide service fees paid by manufacturers to wholesalers, Group Purchasing Organizations or retail community pharmacies
All sales, discounts, rebates, payments or other financial transactions received by, paid by, or passed through to retail community pharmacies ^a or entities that conduct business as wholesalers, including specialty pharmacies, home infusion pharmacies and home healthcare providers, except as specified in 'excluded sales/discounts'	Reimbursement by manufacturers for recalled, damaged, expired or otherwise unsalable returned goods.
	Payments received from and rebates or discounts provided to: PBMs, managed care organizations (MCOs), health maintenance organizations (HMOs), MCO or HMO operated pharmacies, insurers, hospitals, outpatient facilities, inpatient and outpatient hospices, prisons, clinics, mail order pharmacies, long term care providers, nursing home pharmacies, charitable and not-for-profit pharmacies, other manufacturers, direct sales to physicians and patients, any other entity that does not conduct business as a wholesaler or retail community pharmacy (except drugs that are inhaled, infused, instilled, implanted or injected, not generally dispensed through a retail community pharmacy, referred to as '5i drugs').
	Discounts provided by manufacturers under the Medicare Coverage Gap Discount Program
	Sales to Indian Health Service, Department of Veterans Affairs, a State home receiving funds under 38 USC 1741, Department of Defense, the Public Health Service, 340B covered entity, government pharmacies
	Sales under Federal Supply Schedule, TRICARE depot, Federal government award contract
	Sales outside the United States
	Sales, associated rebates, discounts or other price concessions paid directly to insurers.
	Rebates under the national rebate agreement or a CMS-authorized State supplemental rebate agreement paid to State Medicaid Agencies
	Free goods not contingent upon any purchase requirement
	Manufacturer coupons to a consumer, but only if full value of coupon is passed on to consumer, and pharmacy, agent or other entity does not receive any price concession
	Manufacturer vouchers
	Prices negotiated under Manufacturer-sponsored drug discount programs
	Goods provided free of charge under Manufacturer-sponsored patient refund/rebate, copayment assistance and patient assistance programs

^a Retail community pharmacy means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy licensed as a pharmacy by the state and that dispenses medications to the general public at retail prices. The term 'retail community pharmacy' does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies or pharmacy benefit managers.

Source: Medicaid Program: Covered Outpatient Drugs, CMS-2345-P, February 2, 2012 5 Arnold & Porter Client Advisory. Medicaid Rebates: CMS Releases the Long-Anticipated Proposed AMP Rule. January 2012.⁵⁵

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Budget Office (CBO) estimated that the acquisition cost to retail pharmacies averages approximately 4% above the AMP for brand name drugs without generic equivalents.³

In another effort by the federal government to eliminate AWP as a payment benchmark, the Deficit Reduction Act of 2005 (DRA) mandated that AMP instead of AWP be used for the calculation of the FUL. FUL is the maximum amount of pharmacy reimbursement for product costs for certain generic and multiple source drugs that the federal government will recognize in calculating federal matching funds for payment to state Medicaid programs. Congress mandated that CMS follow a formal rulemaking process to outline a clear, consistent definition of AMP for manufacturers. In July 2007, CMS published a final rule that broadly defined the retail class of trade, including community pharmacies as well as mail-order pharmacies, physician offices, outpatient facilities, and other outlets that sell drugs to the general public. The rule did not include pharmacy benefit management companies (PBMs), long-term care facilities, or federal drug benefit programs within the definition of “retail class of trade.” This broad definition led to industry dissent and even legal challenges to AMP use, related to the fairness of a single rate for reimbursement when all of the providers cannot buy at similar rates.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Public Law 110-275) delayed the implementation of new Medicaid payment limits to retail pharmacies using the AMP for multiple-source (generic and brand) drugs⁵⁴ and instructed the Secretary of the Department of Health and Human Services (DHHS) to suspend through September 30, 2009, the planned publication of AMP data submissions on a public Web site.

In March 2010, the Patient Protection and Affordable Care Act (PPACA, PL 111-148) changed the definition of AMP, to represent the average price paid to the manufacturer by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer. PPACA excluded certain payments and rebates or discounts provided to certain providers and payers from calculation of AMP, including wholesaler customary prompt pay discounts, certain bona fide services fees, manufacturer reimbursement for unsalable returned goods, and payments, rebates or discounts related to entities that do not conduct business as a wholesaler or retail community pharmacy.

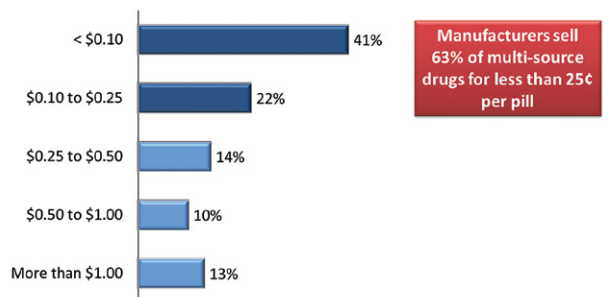
In August 2010, the Education Jobs and Medicaid Assistance Act (PL 111-226) amended the definition of average manufacturer price to include any drug that is an inhalation, infusion, instilled, implanted and injectable drugs (together referred to as “5i drugs”) not generally dispensed through

retail community pharmacies ‘to ensure than an AMP could be calculated and Medicaid rebates could be collected from manufacturers’ for these types of products. Sales, discounts, rebates, payments and other financial transactions must be reported with respect to 5i drugs sales to physicians, PBMs where the PBM is not acting as an insurer, MCOs, HMOs, insurers, hospitals, clinics and outpatient facilities, mail order pharmacies, long term care providers, hospices, and manufacturers who conduct business as a wholesaler or as a retail community pharmacy.

AMP, like ASP, is based on manufacturer reported sales data. In a proposed rule which appeared in the Federal Register on February 2, 2012 (Medicaid covered outpatient drugs, CMS-2345-P), CMS proposed that manufacturers be required to use a 12-month rolling percentage—a process similar to that used in calculating ASP—to estimate the value of lagged price concessions in their calculations of the monthly and quarterly AMPs.⁵ PPACA requires the website public posting of the weighted average of the most recently reported monthly AMPs and the average retail survey price determined for each multiple source drug. Exhibit II-2 shows average weighted AMPs as posted to the CMS website in August 2012.

EXHIBIT II-2. EXAMPLE OF AVERAGE MANUFACTURER PRICES FOR ORAL SOLID GENERIC DRUGS, FOR AUGUST 2012

Per-Unit Average Manufacturer Prices for Oral Solid Generic Drugs, August 2012



Source: Pembroke Consulting analysis of Draft Affordable Care Act Federal Upper Limits for February 2012. Analysis based on 952 product groups. Oral solid products only.

Published on Drug Channels (<http://www.DrugChannels.net>) on November 8, 2012.

Source: Post-election AMP analysis—generic prices are falling. Fein A. Drug Channels. Available at <http://www.drugchannels.net/2012/11/post-election-amp-analysis-generic.html>. Accessed January 28, 2013.

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Federal Upper Limit

The Deficit Reduction Act of 2005 (DRA) mandated that AMP instead of AWP be used for the calculation of the federal upper limit (FUL), the maximum amount of pharmacy reimbursement for product costs for certain generic and multiple-source drugs that the federal government will recognize in calculating federal matching funds for payment to state Medicaid programs. That is, Federal Medicaid matching funds to states are limited to payments that do not exceed the FUL in the aggregate for multiple-source drugs, plus a dispensing fee set by each state. The FUL list is created and maintained by CMS for use by states in their Medicaid Pharmacy programs, but it is also in the public domain for use by any entity.

Effective October 1, 2010, PPACA revised the Social Security Act to require HHS to calculate the FUL as no less than 175% of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer price (AMP) for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. In a study published October 2012, the Office of Inspector General reported that FUL amounts based on published prices were more than four times total pharmacy acquisition costs; and that AMP-based FULs were 61% lower than published price-based FULs at the median.⁵⁶

CMS has proposed that FUL be a unit price calculated for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, meaning A-rated in the FDA Orange Book.⁵ “Initially a FUL will not be published for any FUL group that does not contain at least three innovator and/or non-innovator drug products at the NDC-9 level, that are “A rated” with three monthly AMP prices with AMP units greater than zero reported and certified by manufacturers to calculate the weighted average of monthly AMPs.”⁵⁷

CMS has issued draft AMP-based FUL reimbursement files for review and comment, for multiple source drugs, including the draft methodology used to calculate the FULs.^{57, 58} Because posted monthly AMP-based FULs fluctuated significantly month-to-month, CMS created an alternative methodology based on a rolling three-month average of the monthly AMP-based FULs.⁵⁷ However, the monthly and three month rolling average FUL files do not exactly match, because CMS does not have three months of data for all drugs, and because the older data may be less reflective of pharmacies’ current purchase price as of publication of this *Guide*. These results are posted on the CMS website for review and comment. Until the draft is finalized, CMS is using the prior formula of 150% of the lowest published price as an “interim methodology” to calculate FULs.⁴

Best Price

Medicaid best price was created by OBRA 90 and took effect January 1, 1991 in the calculation of rebates that manufacturers are required to pay to the states and the federal government for sales of single-source and multiple-source branded products to Medicaid beneficiaries.⁶⁰ According to a Congressional Budget Office (CBO) report published in June 2005, best price for brand-name drugs approximates 63% of AWP.⁷⁴

Best price means, with respect to an outpatient single source drug or innovator multiple source drug, the lowest unit price available from the manufacturer to any entity in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price is calculated to include all sales and associated rebates, discounts and other price concessions provided by the manufacturer to any entity unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation from the rebate calculation.

Prices included in best price:^{55, 60}

- Prices to wholesalers
- Prices to any retailer, including rebates, discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs
- Prices to providers (for example, hospitals, HMOs/MCOs, physicians, nursing facilities, and home health agencies)
- Prices available to non-profit entities
- Prices available to governmental entities within the United States
- Prices of authorized generic drugs
- Prices of sales directly to patients
- Prices available to mail order pharmacies
- Prices available to outpatient clinics

Prices excluded from best price:^{55, 60}

- Indian Health Service, Department of Veterans Affairs, a State home, the Department of Defense
- Prices charged under the 340B drug pricing program to a 340B Public Health Service covered entity
- Any prices charged under the Federal Supply Schedule
- Any prices provided to a designated State Pharmaceutical Assistance Program
- Any depot prices and single award contract prices of any agency of the Federal Government

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- Any prices charged which are negotiated by a Part D prescription drug plan, a Part C MA–PD plan with respect to covered Part D drugs, or a Qualified Retiree Prescription Drug Plan
- Rebates under the national rebate agreement or a CMS-authorized supplemental rebate agreement paid to State Medicaid Agencies
- Prices negotiated under a manufacturer-sponsored drug discount card program
- Manufacturer coupons redeemed by a consumer, agent, pharmacy or another entity acting on behalf of the manufacturer, to the extent that the full value of the coupon is passed on to the consumer, and on condition that the pharmacy, agent, or other entity does not receive any price concession
- Goods provided free of charge under a manufacturer’s patient assistance program
- Free goods, not contingent upon any purchase requirement
- Manufacturer vouchers
- Manufacturer-sponsored patient refund/rebate programs
- Sales outside of the United States and its territories
- Discounts provided under the Medicare Coverage Gap Discount Program
- Nominal prices to certain entities (see Glossary; generally defined as manufacturer sales at less than 10% of AMP).
- Reimbursement by manufacturer for recalled, damaged, expired or otherwise unsalable returned goods, including but not limited to reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics and drug destruction.
- Bona fide service fees paid by manufacturers to wholesalers, retail community pharmacies or to any other entity that conducts business as such an entity, or to Group Purchasing Organizations, including but not limited to inventory management fees, product stocking allowances, and fees associated with administrative agreements and patient care programs
- PBM rebates, discounts, or other financial transactions except their mail order pharmacy’s purchases or where rebates, discounts, or other financial transactions except their mail order pharmacy’s purchases, where designed to adjust prices at the retail or provider level

For calculation of the Medicaid rebate, best price is applied when the per unit price to a purchaser is less than the price with the mandatory discount plus any penalties (i.e., greater than 23.1% of current quarter AMP for innovator brands or 17.1% of current quarter AMP for blood clotting factors or for drugs approved exclusively for pediatric indications, plus the Consumer Price Index-Urban [CPI-U] penalty based on launch date).⁶¹

In December 2008, the CBO suggested elimination of the best price provisions, saying that “although many manufacturers offer large discounts to private purchasers, the best price provision discourages manufacturers from offering discounts larger than the flat rebate because such discount automatically triggers a larger rebate to Medicaid.”³ In addition, some providers and health plans have criticized best price as a barrier to the negotiation of lower prices between manufacturers and private-sector customers because manufacturers are reluctant to create new best prices in the Medicaid market.^{62, 63}

Maximum Allowable Cost or Maximum Reimbursement Amount

Maximum allowable cost (MAC), also referred to as Maximum Reimbursement Amount (MRA), is typically a reimbursement limit per individual multiple-source pharmaceutical, strength and dosage form (e.g., \$0.50 per fluoxetine 20 mg capsule). MAC price lists are established by health plans and PBMs for private sector clients and by many states for multiple-source pharmaceuticals paid for by their Medicaid and other state-funded programs. Private sector MACs are considered confidential. While clearly defined in FUL for Medicaid, there is no standardized private sector definition, methodology, update timing or market application for MAC.

Medicaid generic drug cost containment in some states is built around MAC programs. Those programs create their own lists of maximum reimbursement prices for generic drugs. As a general rule, State MAC lists include more drugs and establish lower reimbursements than the FUL list because they are not bound by the FUL three-drug/three-supplier rule, nor by the FUL payment methodology. For a drug on the FUL list, the state MAC can be lower but not higher than the FUL.

National Average Retail Price and National Average Drug Acquisition Cost

State Medicaid programs currently reimburse pharmacies for covered outpatient drugs based, in part, on the estimated acquisition cost (EAC). The EAC, is defined in regulation as the agency’s best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers. On February 2, 2012, in CMS-2345-P, CMS

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proposed replacement of EAC with actual acquisition cost (AAC), “in part because we believe that using the AAC in determining the drug ingredient component of the reimbursement formula will be more reflective of actual prices paid, as opposed to unreliable published compendia pricing”, and further proposed that the AAC be estimated through survey of pharmacy providers.⁶⁴

Myers & Stauffer has been engaged by CMS to provide state Medicaid agencies with acquisition costs and consumer purchase prices of covered outpatient drugs dispensed by pharmacies (not including specialty pharmacies), through a recurring pharmacy survey described in “Survey of Retail Prices: Payment and Utilization Rates and Performance Rankings”. One survey objective is to collect data for calculation of National Average Retail Price (NARP), a monthly pricing database of actual drug prices from independent and chain pharmacies in the United States, including cash paying customers, customers with commercial third party insurance, and Medicaid customers.⁶⁵ A second survey objective is to collect data on the purchase prices of all Medicaid covered outpatient drugs by independent community pharmacies and chain pharmacies, for calculation of the National Drug Acquisition Cost (NADAC).⁶⁶

A recent survey of State Medicaid programs shows that eight states plan to adopt “Average Actual Acquisition Cost” reimbursement methodology for pharmacy ingredient cost.⁶⁷

CMS has proposed replacing the term “dispensing fee” with “professional dispensing fee” and requiring States to reconsider their dispensing fee methodologies when changing their payment for drug ingredient cost. Some states have performed pharmacy “cost to dispense” studies and have adjusted to survey-supported dispensing fees to provide pharmacies a dispensing fee that acknowledges their observed cost to dispense.⁶⁸

Evidence that payment for the drug product has been subsidizing pharmacy overhead to dispense the prescription is found in the new dispensing fees paid in states that have adopted AAC methodology. In the five states that have acted as of this writing (Alabama, Oregon, Idaho, Iowa and Louisiana), dispensing fee payments have doubled or tripled based on cost surveys and research done by the Medicaid programs in those states.

340B

Public Health Service (PHS or 340B) price is the highest price that a ‘340B-covered entity’ could be charged, and is equal to the price that the state Medicaid agency would pay absent any supplemental discount or rebate. The price could be negotiated lower by the 340B entity. However, 340B pricing can be better than Medicaid pricing because sales do not include retail

pharmacy markups and because 340B providers usually negotiate sub-ceiling prices.¹³ 340B prices for brand-name drugs were reported to average 51% of AWP (see Exhibit II-2).

PPACA expanded the 340B program to include certain children’s hospitals, freestanding cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals.⁶⁹ PPACA exempted pharmaceutical manufacturers from having to provide discounts on orphan drugs to these newly eligible entities. In May 2011, HRSA published a proposed rule to clarify how orphan drugs can be purchased under the 340B program (76 Fed. Reg. 29,183, 5/20/11). Under the proposed rule, orphan drugs are excluded from the 340B program for newly eligible entities, if the drugs are used to treat diseases for which they received orphan-drug designation. Newly eligible covered entities could purchase orphan drugs at the 340B prices “when using them for common conditions for which they are approved or any other lawful use except when using them for the rare condition or disease for which they were given an orphan drug designation by the FDA.”

The following are 340B eligible entities, including those which PPACA made eligible:⁷¹

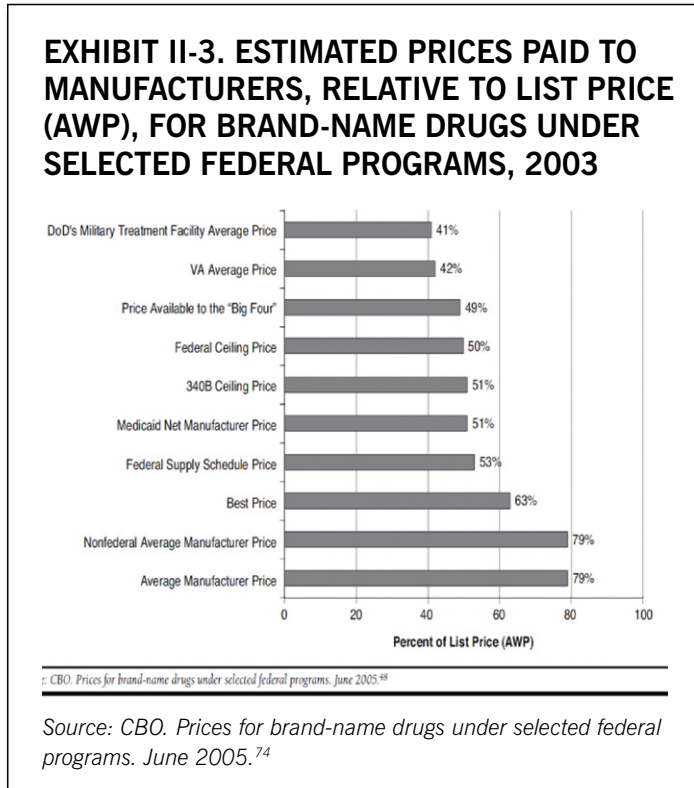
- Federally Qualified Health Centers (FQHC)
- Comprehensive Hemophilia Treatment Centers
- Ryan White Programs (Parts A, B, C, D)
- Sexually Transmitted Disease/Tuberculosis Programs (STD/TB)
- Title X Family Planning Clinics
- Urban / 638 Tribal Programs
- Federally Qualified Health Center Look-Alikes (FQHC-LA)
- Disproportionate Share Hospitals (DSH)
- Children’s Hospitals
- Free Standing Cancer Hospitals
- Critical Access Hospitals
- Sole Community Hospitals
- Rural Referral Centers

Patients of a covered 340B entity, including non-Medicaid patients, may receive drugs purchased at the 340B discount price. The benefit of this preferred pricing may be realized by the patient, the payer, the 340B entity, or shared among the parties. However, covered entities are not permitted to resell or transfer outpatient drugs purchased at the 340B discount to individuals who are not patients of the covered entity.⁷² HRSA projects that as of October 2013, there will be almost 20,000 340B covered entities in the United States, with more joining each year.⁷³

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■ ■ Comparison of Benchmark Prices

Exhibit II-3, from a 2005 CBO study, shows how selected benchmark prices compare with both AWP and each other.



Benchmarks and the Goal of Appropriate Payment

The “best” benchmark will be defined by its purpose and accuracy in defining a common value at a given point in the chain of drug distribution and at a particular point in time. The best benchmark may be different for government versus private payers. Some factors that should be considered when defining benchmarks include the following:

- At what point in the distribution chain is the benchmark the most accurate determination of the common true price? For

example, a benchmark based on average actual transaction price should accurately reflect the most common selling price, while a benchmark based on average net acquisition cost should represent the most common prices for wholesalers or providers as purchasers. How accessible, transparent, and accurate are the benchmark values for all stakeholders?

- AWP and WAC have been used as drug payment benchmarks because they were readily accessible from Medi-Span, Redbook, and First Databank. However, AWP has been shown to have almost no relevance to the net price of most generic drugs, and WACs have not been readily accessible in all cases, mainly for generics. Also, these terms cannot be interpreted literally; that is, AWP does not generally represent the price of a drug purchased from a wholesaler, and WAC does not generally represent the actual cost to the wholesaler.⁷⁵
- How will different stakeholders be affected by the change? For example, if average actual transaction price is used as a benchmark for calculation of provider compensation, is there recognition of the cost that is added in the process of transferring the product from manufacturer to provider, representing the value added as the product passes through the channels of distribution?
- What are the consequences for other payment methods? For example, how would use of AMP as a pricing benchmark for provider reimbursement affect Medicaid rebates and rebate-discount negotiations between private payers and pharmaceutical manufacturers?
- What will be necessary for individual payers to monitor, modify, and administer the new payment method? For example, how much will the benchmark vary among smaller versus larger providers or among various Classes of Trade (COTs)? How can these variations be monitored and adjusted if desired to best represent actual price for different types of purchasers? What administrative burden will be incurred by monitoring the reasonableness of prices for different types of purchasers?

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The following compares pros and cons for several pricing benchmarks currently in use:

Benchmark	Pros	Cons
Average Wholesale Price (AWP)	Nationally standardized price, widely accepted, frequently updated, comprehensive	Not transparent, not reflective of actual prices, subject to manipulation, not durable at this time
Average Acquisition Cost (AAC)	Represents average true acquisition cost from targeted purchasers on a transactional basis, includes discounts and rebates, comprehensive	Varies by purchasing entity (chain vs. independent), not standardized as prices will vary from state to state, etc., not frequently updated, high administrative burden, may require legislation to implement
Average Sales Price (ASP)	Transactional basis calculated by CMS, weighted average prices	Not comprehensive as use was intended for Medicare Part B drugs, not frequently updated, considerable lag time in reporting, not stratified for class of trade, not transparent
Average Manufacturer Cost (AMP)	Transactional basis calculated by CMS, specific per NDC, comprehensive	Only weighted average AMP, not NDC-specific AMP, is publicly available, considerable lag time in reporting, no transparency
Wholesale Acquisition Cost (WAC)	Nationally standardized price (codified in legislation), broadly accepted, brands frequently updated, tied to supplemental rebates (increases to WAC will result in increases in supplemental rebates)	Semi-transparent, no oversight, not reflective of actual prices for brand or generic (but closer than AWP for brand), not comprehensive, generics not frequently updated, NCPDP endorsed replacement benchmark

III. Payers and Payment Methods

Payment to providers for the prescription drugs they administer and dispense varies depending on the payer and the site of care. Each combination of payer and site of care may involve a different reimbursement formula. As a result, providers must be keenly aware of their payer “mix,” the portion of total revenue attributable to each type of payer. Payers have an important economic stake in the treatment setting in which a particular drug is prescribed or administered.

■ ■ Medicare

Background

Medicare, established in 1965 as a federal health insurance program available to individuals who fall into one of three specified categories defined by age, disability, or end-stage renal disease (ESRD), has several statutory benefit programs: Part A (hospital insurance), Part B (medical insurance), Part C (Medicare Advantage), and Part D (prescription drug coverage). Each program has unique rules governing coverage and payment methods for prescription drugs. In general, the payment method will depend on the treatment setting.^{76, 77}

- Hospital inpatient
- Hospital outpatient department (HOPD)
- Physician office
- Dialysis facility
- Ambulatory surgical center (ASC)
- Skilled nursing facility
- Home (via home health provider)
- Home (via retail or mail-order pharmacy)
- Telehealth

Medicare’s Influence on Prescription Drug Payment

Private health insurance pays the largest portion of prescription drug costs, and available data show that this remains the case despite introduction of Medicare Part D in 2006. As of 2011, private health insurance and other third parties are expected to pay 44.6% and public funds (i.e., Medicare, Medicaid, and other public funds) to pay for 37.8% of prescription drug sales in retail outlets, while beneficiary out-of-pocket is expected to pay the balance.⁷⁸

The following provides a brief overview of Medicare payment in selected treatment settings.⁷⁶

Hospital Outpatient Departments

Medicare reimburses HOPDs by using the outpatient prospective payment system (OPPS). Under the OPPS, CMS classifies services into ambulatory payment classifications (APCs) on the basis of clinical and cost similarity. All services within an APC maintain the same payment rate.⁷⁹

Drugs, biologics and radiopharmaceuticals whose cost per day is \$80 or less (in 2013) are “packaged” or “bundled” into APCs for the procedures in which they are used, meaning that there is no separate reimbursement for those drugs. Drugs, which CMS calls “specified covered outpatient drugs” (SCODs), and radiopharmaceuticals exceeding the \$80 threshold receive separate payment through drug-specific APCs. As of January 1, 2013, the payment amount is ASP plus 6%, identical to the physician office payment rate.⁸⁰ Drugs eligible for transitional pass-through payment are also paid at ASP plus 6%. CMS may change these payment rates annually. Please note the impact of the Federal Government Sequester on ASP markup for the claims dated on or after April 1, 2013, as discussed earlier in the *Guide*.

Physician Offices

Following passage of the MMA, Congress and CMS reduced payments for drugs and increased payments for intravenous infusions and other drug administration services. ASP replaced AWP as the drug reimbursement benchmark. Payment for most physician office drugs is currently ASP plus 6%. Section II, “Payment Benchmarks,” describes how ASP is calculated and reported.

Pharmacy-Dispensed Medicare Part B Drugs

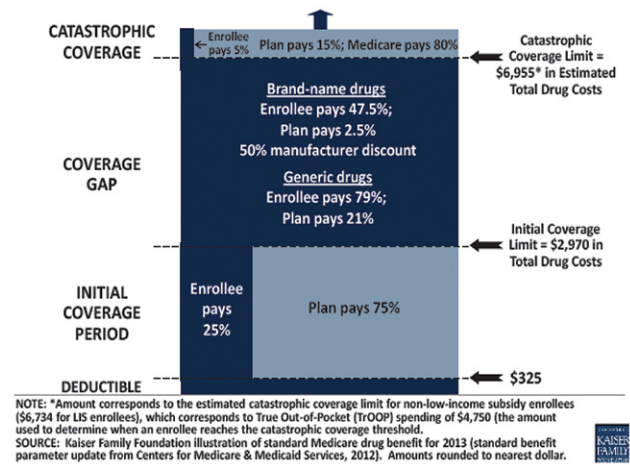
The vast majority of Part B drugs are administered in a physician’s office, clinic or HOPD; however, some drugs dispensed by retail or mail-order pharmacies for self-administration also are part of the Part B benefit. Examples are: immunosuppressives to prevent organ transplant rejection, drugs used with durable medical equipment like pumps and nebulizers, hemophilia clotting factors, some vaccines and some oral cancer drugs. In other situations, a drug that is typically a Part D covered drug could instead be covered under Part B because of how or where it is used. Medicare publishes several helpful lists to identify the situations when a drug could be covered by Part B or Part D. See appendix C-1 in chapter 6 of the Medicare Part D Manual⁸² and a table that identifies Medicare coverage of medically-necessary drugs in some common situations. The reimbursement rate for pharmacy-dispensed Part B drugs is currently ASP plus 6%.^{84, 85}

Pharmacy-Dispensed Medicare Part D Drugs

Part D is administered by private-sector entities, either stand-alone Prescription Drug Plans (PDPs) or Medicare Advantage–Prescription Drug plans (MA-PDs). These plans compete for enrollees on the basis of annual premiums, benefit structures, specific formulary drugs, pharmacy networks, and quality of services. PDPs and MA-PDs are typically PBMs and commercial health plans. The Medicare trust fund board of trustees projects that in 2012, approximately 8.5% of Part D enrollees nationwide (6.9 million of a total of 37.2 million) were Medicaid full dual eligibles (i.e., enrolled in both Medicare and Medicaid) who are automatically enrolled in Part D and randomly assigned to Part D plans.^{86, 87} Exhibit III-1 shows sources of Medicare beneficiary drug coverage.

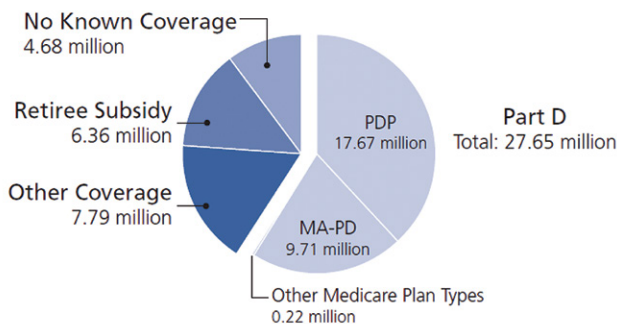
There is no direct Medicare reimbursement for Part D drugs. Revenue for MA-PDs and PDPs comes from beneficiary premiums and cost sharing via copayments or coinsurance, manufacturer discounts of brand drugs in the coverage gap, as well as from Medicare subsidy and reinsurance payments. Medicare payments to PDP and MA-PD plans are determined through a competitive bidding process, and enrollee premiums are also tied to plan bids.⁸⁸ Exhibit III-2 shows the structure of the standard Part D benefit, including reduced cost-share for 2013 in the ‘donut hole’ as discussed in the next section of the Guide, titled ‘The Part D Coverage Gap’.

EXHIBIT III-2. STANDARD MEDICARE DRUG BENEFIT, 2013



Source: Prescription drug benefit fact sheet. November 2012. Kaiser Family Foundation. Available at <http://www.kff.org/medicare/upload/7044-13.pdf>. Accessed January 17, 2013

EXHIBIT III-1. SOURCES OF MEDICARE BENEFICIARY DRUG COVERAGE, 2010



Note: Numbers may not add due to rounding.
Source: Centers for Medicare & Medicaid Services, “2010 Enrollment Information,” ZIP files; available at www.cms.hhs.gov/PrescriptionDrugCovGenInl.

Source: The Medicare Drug Benefit (Part D). National Health Policy Forum. Coberly S. January 15, 2013. Available at http://www.nhpf.org/library/the-basics/Basics_PartD_01-15-13.pdf. Accessed January 17, 2013.

The Part D Coverage Gap

PPACA reduces beneficiary cost sharing in the Part D coverage gap (also known as the “donut” or “doughnut” hole) to 25 percent by 2020, as shown in the exhibits III-3 and III-4. People with Medicare who have Part D, but who do not receive the low-income subsidy, will get a discount (50% in 2012) under the Medicare Coverage Gap Discount Program on “applicable” drugs (i.e., Part D prescription drugs approved under new drug applications or licensed under biologics license applications, including insulin and Part D vaccines and generics FDA-approved under NDAs) at the point-of-sale and an increase in coverage for all other covered Part D drugs (e.g., generic drugs and supplies associated with the delivery of insulin) while they’re in the coverage gap.⁸⁹

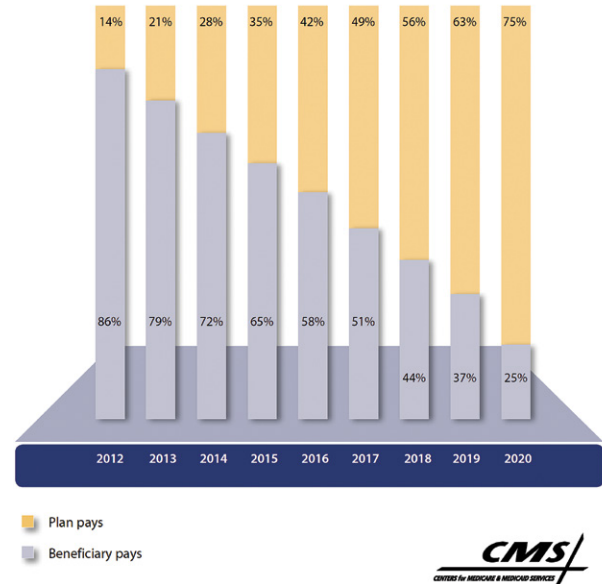
According to the Employee Benefits Research Institute, yearly reduction in coinsurance due to closing of the coverage gap will reduce savings needed for health care expenses in retirement for individuals with the highest prescription drug use.⁹⁰

Medicare Payment to PDPs

For 2013, it is projected that Part D enrollees who are not dual eligibles will pay an average of \$393 per year in premiums, which is about 25% of the expected Medicare Part D benefit expenditures per person. CMS subsidizes the remaining 75% of the cost of standard coverage for all types of beneficiaries. That average subsidy takes three forms.^{91, 87}

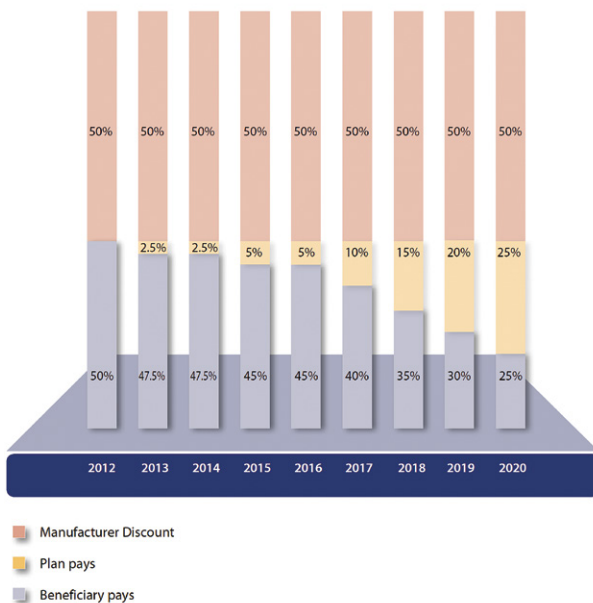
1. Direct subsidy: A monthly prospective payment.
2. Individual reinsurance: If a beneficiary exceeds the catastrophic threshold, CMS subsidizes 80% of drug spending above the threshold, and the plan is at risk for the remaining 20%. Medicare establishes “risk corridors” to limit a plan’s overall losses or profits (see Exhibit III-3). By using risk corridors, Medicare limits a plan’s potential loss (or gain) by financing some of the higher-than-expected costs (or recouping excessive profits). These corridors are scheduled to widen, meaning that plans should bear more insurance risk over time.

EXHIBIT III-4. GENERIC DRUG SAVINGS IN THE COVERAGE GAP



Source: Closing the coverage gap. CMS. <http://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/downloads/11522-P.pdf>. Accessed January 18, 2013.

EXHIBIT III-3. BRAND-NAME PRESCRIPTION DRUG SAVINGS IN THE COVERAGE GAP



Source: Closing the coverage gap. CMS. <http://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/downloads/11522-P.pdf>. Accessed January 18, 2013.

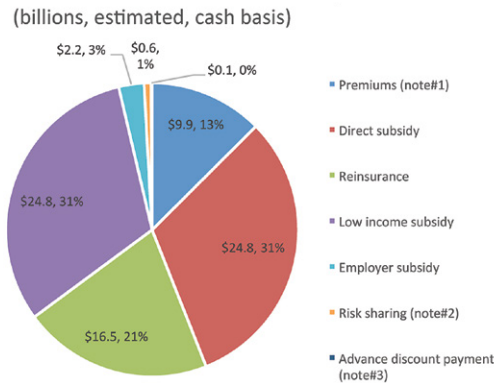
3. Low income subsidy: For plans that enroll low-income beneficiaries, Medicare pays some of their enrollees’ cost sharing and premiums.

The total projected Part D cost for 2013 is estimated to be \$79 billion, broken out as shown in exhibit III-5.

In 2013, the Medicare Trustee Report⁷³ estimates pharmaceutical manufacturer rebates in Part D at 10.6% of total prescription drug costs, down from 11.3% in 2010, and estimated to reduce further to 10.3% by 2021 due to loss of patent protection for some of the drugs with the highest Part D rebate amounts.

The 2003 Medicare Prescription Drug, Improvement, and Modernization Act (MMA) (Public Law 108-173) established risk corridors partly to protect PDPs from higher than expected costs, but also to recoup excessive payments. Risk corridors were defined in the statute as “specified percentages above and below a target amount. The target amount is defined as total payments paid to the plan, taking into account the amount paid by CMS and enrollees, based on the standardized bid amount, risk adjusted, and reduced by total administrative expenses assumed in the bid.

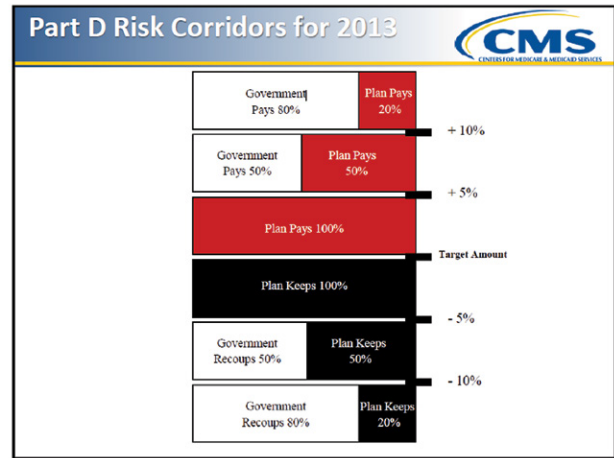
EXHIBIT III-5. AGGREGATE PART D REIMBURSEMENT AMOUNTS, CY 2013



1. Total premiums paid to Part D plans by enrollees (directly, or indirectly through premium withholding from Social Security benefits).
2. Positive amounts represent net loss-sharing payments to plans, and negative amounts are net gain-sharing receipts from plans. These amounts may include the delayed settlement of risk sharing from prior years.
3. The advanced discount payment serves as loans to plans for the 50 percent ingredient cost discount on brand name drugs in the coverage gap. The plan sponsors will reimburse Part D back once they receive the payments from the drug manufacturers.

Source: Medicare Trustee Report 2012, table IV,B11⁷³

EXHIBIT III-6. PART D RISK CORRIDORS FOR 2013



Source: CMS 2012 Regional Technical Assistance Presentation Slides. A Reddix & Associates. Available at [http://www.csscooperations.com/Internet/Cssc3.Nsf/files/2012%20PDE%20Regional%20TA%20Slide%20Presentations.pdf/\\$File/2012%20PDE%20Regional%20TA%20Slide%20Presentations.pdf](http://www.csscooperations.com/Internet/Cssc3.Nsf/files/2012%20PDE%20Regional%20TA%20Slide%20Presentations.pdf/$File/2012%20PDE%20Regional%20TA%20Slide%20Presentations.pdf). Accessed January 18, 2013 92

for the 100 brand-name drugs (\$2.9 billion vs. \$4.5 billion), despite having only about one-fourth of the expenditure (\$6.4 billion vs. \$24 billion).⁹³

At this time, Part D vendors negotiate their own rebate arrangements with drug manufacturers, in exchange for preferred positioning on drug formularies and preferred drug coverage policies. The OIG has estimated a 19% overall discount for vendors in Part D, compared to a 45% discount in Medicaid.⁹⁴ It has been suggested that Part D utilization by enrollees who are dual eligibles or are eligible for Low Income Subsidy be made subject to Medicaid-level drug manufacturer rebates, and that this would save the Federal government almost \$137 billion over 10 years. Pushback includes that because this change would impact 56% of Part D spending, it would have significant consequences, potentially including higher Part D premiums, cost-shift to higher cost drugs outside of Medicare Part D, poorer quality Part D formularies, and lower R&D investment for impacted drugs.¹⁶

Because PDPs are at partial risk for the drug costs of their beneficiaries, they are primarily concerned with controlling drug spending within the parameters of appropriate therapeutic use of these agents. Thus, PDPs may be less motivated or enticed by manufacturer rebates on products that might increase drug spending compared with therapeutic alternatives. PDPs are insulated and separated from the medical care cost component. For the same reason, PDPs also may be less motivated than MA-

No payment adjustments are made if adjusted allowable costs for the plan are at least equal to the first threshold lower limit of the first risk corridor but not greater than the first threshold upper limit of the risk corridor for the year (i.e., if the plans are within the first risk corridor). A portion of any plan spending above or below these levels is subject to risk adjustment. If adjusted allowable costs exceed the first threshold upper limit, then payments are increased. If adjusted allowable costs are below the first threshold lower limit, then payments are reduced. Adjusted allowable costs are reduced by reinsurance and subsidy payments (see Exhibit III-6).⁹²

In a study of 2009 data published in August 2011, the OIG found that statutory Medicaid rebates for brand-name drugs substantially exceeded Part D rebates, despite that Part D sponsors and State Medicaid agencies paid pharmacies similar amounts for most brand-name drugs reviewed. "As a result, Medicaid collected nearly two-thirds as much as Part D in rebates

PDs by a manufacturer claim justifying a higher-net-priced drug being offset by reduced utilization of other health care system resources, such as hospitalization, emergency room or physician office visits.

PDP Report to CMS of “Lock-In price” Versus “Pass-Through Price.” Part D plan sponsors are required to report drug costs (the “negotiated price”) to CMS. Effective January 1, 2010, CMS ruled that Part D plan sponsors must report as “negotiated price” the price actually paid to pharmacies, and that Part D sponsors must charge beneficiaries the lesser of a drug’s negotiated price or the applicable copay. CMS replaced the term “negotiated price” with “actual cost,” defined as “the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out of network pharmacy” The negotiated price (actual price) is used to determine any CMS reinsurance or risk corridor payments.⁹⁶

Pharmaceutical Manufacturer Price Negotiations. The law creating the Medicare Part D drug benefit specifically prohibited CMS from negotiating prices directly with manufacturers. Part D price negotiations with manufacturers are handled by PDPs and MA-PDs. There have been efforts in Congress to pass legislation which would allow Medicare to negotiate price concessions directly with pharmaceutical manufacturers for Part D, in the belief that greater discounts could be gained.⁹⁷ The President’s Health and Human Services Fiscal Year 2013 budget proposed that Medicare benefit from the same rebates that Medicaid receives for brand name and generic drugs provided to beneficiaries who receive the Part D Low-Income Subsidy, beginning in 2013, estimating that this would yield \$155.6 billion in savings over 10 years.⁹⁸ To date, these efforts have been unsuccessful.

Medicare Part B or Part D. Medicare payment for more than a dozen categories of pharmaceuticals, including immunosuppressive agents used for transplant patients, parenteral nutrition, intravenous immune globulin (IVIG), and hepatitis C vaccine, could be made under either Part B or Part D. Whether payments fall under either Part B or Part D depends on such factors as diagnosis, route of administration, location of treatment, and whether the drug is self-administered. Whether payment is made under either Part B or Part D determines the payment method used and, thus how much is paid.^{99, 82, 83}

Protected Therapeutic Classes. Plans are allowed to develop formularies that exclude certain drugs from coverage, although they are required to have at least two formulary drugs for each therapeutic category. However, pursuant to CMS guidance, plans are required to include in their drug formularies “all or substantially all” drugs in six protected classes (“six classes of

clinical concern”: immunosuppressant for prophylaxis of organ transplant rejection, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic). “Substantially all” does not include multiple-source brand drugs, extended-release products when the immediate-release product is included, or dosage forms that do not provide a unique route of administration (e.g., tablets vs. capsules). The intent of this policy was to ensure that Medicare beneficiaries who use these drugs would not be discouraged from enrolling in certain Part D plans and would not experience interruption in therapy. Plans may not implement prior authorization or step therapy requirements to steer beneficiaries currently taking a drug to preferred alternatives within these protected classes, but plans may use prior authorization or step therapy for patients who are new to the drug therapy.⁹⁹

Least Costly Alternative

Between 1995 and 2010, certain drugs covered under Medicare Part B were subject to Least Costly Alternative (LCA) policies, which based the payment for a group of clinically comparable drugs on the payment for the least costly one. LCA is essentially a reference price system. Products deemed to be therapeutic alternatives are grouped together under an LCA policy statement. The least costly product, with cost measured as the Medicare reimbursement rate, becomes the reference price for all products covered by the LCA policy. All LCA products are covered; however, regardless of which product is used, the provider is reimbursed as if the least costly product was used. Most of the LCA drug payment impact occurred for a class of prostate cancer treatments known as GnRH (or LHRH) agonists and for inhaled drugs to treat respiratory disease.

In a federal district court decision involving an inhaled drug, the court held that CMS cannot use LCA to set payment for the inhaled drug because Medicare payment is established by statute and LCA runs contrary to the clear and plain language of the statute.¹⁰⁰ Subsequent to the decision, Medicare contractors withdrew their use of LCA for the inhaled drug but have kept LCA in place for the GnRH agonists. The Medicare Payment Advisory Commission concluded that this district court decision may affect Medicare contractors’ ability to apply LCA policy to any drug.¹⁰¹ In April 2010, CMS discontinued all LCA policies for Part B drugs.

In a recent study of the impact of withdrawal of LCA policies in prostate cancer, the OIG found that thereafter, utilization patterns shifted dramatically in favor of certain costlier products. OIG calculated that if LCA policies for LHRH agonists had not been rescinded Medicare expenditures would have been reduced by \$33.3 million over 1 year, from \$264.6 million to \$231.3 million. Based on these findings, OIG recommend that the CMS consider seeking legislative authority to implement LCA policies for Part B drugs under appropriate circumstances.¹⁰²

Home Health and Home Infusion

For drugs infused in the home health setting, the extent of Medicare coverage for those drugs, infusion-related supplies and infusion-related services depends on circumstances, as depicted in Exhibit III-7.¹⁰³

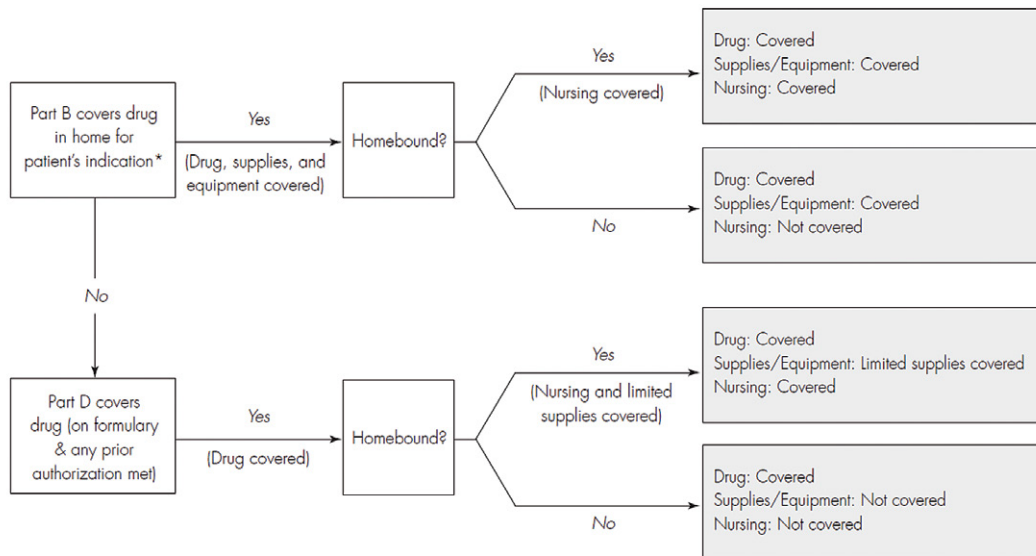
Medicare Part B does not separately reimburse for prescription drugs administered in the home health setting, but certain exceptions exist:^{99, 104, 105}

- **Durable Medical Equipment (DME) Supply Drugs.** DME drugs are covered as a supply necessary for the covered equipment to perform its function. The largest Medicare expenditures for drugs furnished as a DME supply are for inhalation drugs, which are administered in the home through the use of a nebulizer (e.g., albuterol sulfate, ipratropium bromide). Other examples of drugs administered through covered DME in the home setting include parenteral nutrition and some chemotherapeutic agents. Infusion drugs administered in conjunction with DME are one of the few types of drugs that are paid by Medicare Part B using AWP instead of ASPs. The MMA excluded infusion drugs used with DME from the ASP methodology and set their payment

amount at 95 percent of the AWP that were in effect on October 1, 2003. The OIG has recommended that the CMS either (1) seek a legislative change requiring DME infusion drugs to be paid using the ASP methodology or (2) include DME infusion drugs in the next round of the competitive bidding program.¹⁰⁶

- **Immunosuppressive Drugs.** Immunosuppressive drugs (such as cyclosporine) are covered for beneficiaries who have received a Medicare-covered organ transplant.
- **Hemophilia clotting factors.** Hemophilia clotting factors and items related to administration are covered, for hemophilia patients able to self-administer without medical supervision.
- **Oral Anti-Cancer Drugs.** Drugs taken orally during cancer chemotherapy are covered, if they have the same active ingredients and are used for the same indications as non-self-administered injectable chemotherapy drugs.
- **Oral Antiemetic Drugs.** Oral anti-nausea drugs used in place of intravenous antiemetic drugs as part of an anti-cancer chemotherapeutic regimen are covered, if administered within 48 hours of the chemotherapy administration.

EXHIBIT III-7. MEDICARE FEE-FOR-SERVICE COVERAGE FOR HOME INFUSION



Note: A beneficiary who is homebound and who needs part-time or intermittent skilled nursing assistance with home infusion of intravenous drugs would generally meet the Medicare home health benefit eligibility criteria, in which case nursing and in some circumstances limited supplies would be covered. If the drug is not covered by Part B or Part D, a homebound beneficiary would potentially have coverage under the home health benefit for nursing and in some circumstances certain supplies, but not the drug or equipment.
 *Intravenous immune globulin covered in the home under Part B follows different coverage rules than displayed above (only the drug is covered unless the beneficiary is homebound, in which case nursing and, in some circumstances, limited supplies are covered).

Source: MedPAC analysis of Medicare coverage rules.

III. PAYERS AND PAYMENT METHODS

- *Pneumococcal vaccine.* Physician-prescribed vaccine and its administration are covered.
- *Hepatitis B vaccine.* The vaccine and its administration to a beneficiary at high or intermediate risk of contracting hepatitis B are covered.
- *Influenza vaccine.* The vaccine and its administration are covered, upon request without a physician order and without physician supervision.
- *Antigens.* Antigens as prepared by a physician for a specific patient are covered. While generally administered in the physician office, antigens may also be self-administered by the patient at home.
- *Erythropoietin.* When administered for the treatment of anemia for persons with chronic renal failure who are on dialysis, Erythropoietin is included in the ESRD prospective payment.¹⁴
- *Oral ESRD drugs.* Oral ESRD drugs are included in the ESRD prospective payment if the same drug is available in injectable form covered under the Part B ESRD benefit. As of January 2016, ESRD oral drugs not available in injectable form will be added to the ESRD prospective payment.¹⁵
- *Parenteral Nutrition.* Parenteral nutrition, administered via an infusion pump, is covered under the prosthetic benefit.

EXHIBIT III-8. MEDICARE PAYMENT RATES FOR DRUG INFUSIONS BY TREATMENT SETTING*

Medicare payment rates for intravenous drug infusions across settings, 2012

	Inpatient hospital	SNF	HOPD	Physician office	Home health care
Drug	Packaged in DRG payment to hospital	Packaged in SNF PPS payment*	ASP+4%** for drugs with a cost per day greater than \$75 Packaged in the drug administration payment for drugs with a cost per day of \$75 or less	ASP+6%	Paid separately to pharmacy: 95% AWP if DME covered drug ASP+6% if IVIG for PID Part D negotiated rate for other drugs
Supplies and equipment	Packaged in DRG payment to hospital	Packaged in SNF PPS payment	Packaged in payment for administration	Packaged in payment for administration	Limited supply coverage for gravity infusions under home health benefit
Drug administration	Packaged in DRG payment to hospital Payment amount varies depending on patient diagnosis and is not affected by the provision of infusion drugs or in most cases by length of stay	Packaged in SNF PPS payment Per diem rate for relevant RUG groups: \$223.19 or \$261.74 per day (patient needing IV medication) \$281.02 per day (patient with foot ulcers) \$470.55 per day (patient requiring isolation)	\$126.64 first hour \$34.81 each additional hour	\$72.50 first hour \$21.44 each additional hour	Packaged in home health PPS payment \$2,808 for 60-day episode on average if 5+ visits \$112.88 per nurse visit if 4 or fewer visits
Cost sharing	Inpatient hospital deductible of \$1,156	None for days 1–20 and \$144.50 per day for days 21–100	20%	20%	None for home health Part D beneficiary cost sharing is actuarially equivalent to 25% but varies based on formulary tier; where the patient is relative to the deductible, standard benefit, coverage gap, and catastrophic limit; and whether the patient receives the low-income subsidy 20% for DME drugs and IVIG for PID

Note: SNF (skilled nursing facility), HOPD (hospital outpatient department), DRG (diagnosis related group), SNF PPS (skilled nursing facility prospective payment system), ASP (average sales price), DME (durable medical equipment), AWP (average wholesale price), IVIG (intravenous immune globulin), PID (primary immune deficiency), RUG (resource utilization group), IV (intravenous).
*While most drugs are packaged in the SNF PPS payment, certain chemotherapy drugs are paid separately.
**In the hospital outpatient prospective payment system, new drugs receive transitional pass-through status for two to three years during which time they are paid the average sales price plus 6 percent.

Source: MedPAC analysis of Medicare payment rates and cost sharing.

*Note that data in this table is for 2012.

- *Intravenous Immune Globulin Provided in the Home.* The Medicare Modernization Act created a benefit for the provision of intravenous immune globulin (IVIG), only for beneficiaries with a diagnosis of primary immune deficiency disease. At this time, payment is limited to the IVIG itself and does not cover items and services needed for administration. On December 31, 2012, Congress passed the Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012, which was signed by President Obama on January 10, 2013. The Act provides for a three-year demonstration of a Medicare bundled per visit payment for items and services needed for the in-home administration of IVIG for the treatment of primary immune deficiency diseases.¹⁰⁷
- *Injectable Osteoporosis Drugs.* These products are covered for women who have sustained bone fractures who are unable or unwilling to self-inject.

Medicare payment and beneficiary cost share for drug infusion services depends on site of care and on patient and clinical circumstances, as shown in Exhibit III-8.¹⁰³

CMS requires that Part D vendors assure adequate access to home infusion pharmacies in their provider networks.¹⁰⁸ In addition, Part D sponsors that offer Medicare Advantage prescription drug plans may provide Part D home infusion drugs as part of a bundled service, as a mandatory supplemental benefit under Part C. CMS's rationale is that, for Part D sponsors electing to do this, it will "...improve benefit coordination of home infusion therapy between Part C and Part D. This improved benefit coordination promotes continuity of care and cost avoidance of more expensive institutional care by facilitating continuous access to home infusion drugs, as well as the costs of administration and supplies associated with that therapy."⁹⁹

■ ■ Medicaid Background

Medicaid is a program financed jointly by federal and state governments that provides medical and long-term care (LTC) to many of the nation's most vulnerable lower-income individuals, especially mothers and children, seniors, and individuals with disabilities. Medicaid programs, which accounted for 23.6% of state spending in 2011, are under continuing pressure nationwide as a result of reduced state revenues in the face of increased demand because of reduced availability of employer health insurance coverage and, starting in late 2008, increased layoffs in response to a worsening economy.¹⁰⁹

Current eligibility rules for Medicaid vary widely from state to state, and eligibility is linked to income as well as other factors, such as family or disability status. Each state decides how to structure benefits, eligibility, service delivery, and payment rates

within guidelines established by federal law, and subject to waivers of law. Beginning January 2014, PPACA provides States the option to expand Medicaid eligibility to all individuals under age 65 in families with income below 133% of the Federal Poverty Level (FPL). People meeting this income threshold also become eligible, even without meeting other qualifying factors for Medicaid eligibility, such as under age 18, disabled, pregnant or parents of eligible children. However, in accordance with the Supreme Court's ruling,¹¹⁰ States are not required to expand Medicaid eligibility as a condition of continuing to receive Federal financial participation.¹¹¹

State spending on Medicaid is matched by the federal government. The federal financing share—Federal Medical Assistance Percentage (FMAP)—is determined each year based on each state's average per capita income level, compared with the national income average. States with a higher per capita income level are reimbursed a smaller share of their costs. By law, the FMAP cannot be lower than 50% or higher than 83%.

In FY 2012, the FMAPs ranged from 50% in 19 States and the Territories to 74% in Mississippi, and averaged 58.8% overall. An "enhanced" FMAP for children covered through the Children's Health Insurance Program (CHIP) resulted in Federal government reimbursement averaging 71% in FY 2012. The American Recovery and Reinvestment Act (ARRA) of 2009 (Public Law 111-5) increased FMAPs by up to 14% points, depending on state unemployment rates, for the first quarter of FY 2009 through the first quarter of FY 2011. The Education, Jobs, and Medicaid Assistance Act of 2010 (Public Law 111-226) extended these increases, but at lower levels, for the second and third quarters of FY 2011.¹¹¹

PPACA increases FMAPs to up to 100% for certain individuals who are newly eligible for Medicaid beginning in January 2014, and provides increased FMAPs for certain disaster-affected states, primary care payment rate increases, specified preventive services and immunizations, smoking cessation services for pregnant women, specified home and community-based services, and home health services for certain people with chronic conditions.¹¹²

Although not a basic mandatory Medicaid service, every Medicaid program includes an outpatient prescription drug benefit. States pay pharmacy providers directly on a fee-for-service (FFS) basis unless the beneficiary is enrolled in a managed care arrangement, in which case the state pays capitation to the managed Medicaid organization for the beneficiary's care, including pharmacy. State-specific payment formulas including ingredient cost calculation, whether a MAC list applies, dispensing fee amount, and beneficiary cost-share amount are accessible on the CMS Web site.¹¹³ With the availability of prescription drug coverage and low-income subsidies under Part D, Medicaid is no longer the primary payer for prescription drugs for Medicaid

beneficiaries who also have Medicare (referred to as ‘Medi/Medi’ or ‘dual eligibles’). States are required to defray a portion of Part D expenditures for those beneficiaries.¹¹¹

As of July 2011, more than 74% of Medicaid beneficiaries were enrolled in some type of managed care program, including health insuring organizations, commercial managed care organizations, Medicaid-only managed care organizations, Primary Care Case Management, prepaid inpatient health plans, prepaid ambulatory health plans, programs for all-inclusive care for the elderly and others.¹¹⁴ However health insuring organizations, commercial managed care organizations and Medicaid-only managed care organizations represented only 47% of this enrollee pool. In 2011, 16 Medicaid programs carved-out their pharmacy benefit, in whole or in part, from these managed care plans.¹⁹

When pharmacy benefits are carved into Medicaid managed care contracts, CMS requires states to collect drug utilization data, for collection of statutory rebates from pharmaceutical manufacturers. However, in a study conducted in Q2 2011, the OIG found that 10 of 22 states using the carve-in approach did not collect rebates.¹⁹

Every state Medicaid program, either directly or through managed Medicaid organizations, also pays for drugs that are utilized under the medical benefit (e.g., in the physician’s office and clinic). Drugs covered under the medical benefit are typically paid for differently than are drugs covered under the pharmacy benefit, using formulas that vary by state, that are based on AWP, WAC, or ASP. States are required to collect rebates for drugs administered in these settings also, but as of 2009, not all states were in compliance.²⁰

Dual Eligibles (Medi/Medi)

Medicaid beneficiaries who also qualify for Medicare are known as dual eligibles. In 2010, there were approximately 9.9 million dual eligible beneficiaries.¹¹⁵ Nearly 60% of dual-eligible beneficiaries have a mental or cognitive problem, 55% have three or more chronic conditions, and 50% rate their health status as fair or poor. Compared to non-dual eligible beneficiaries, this patient population utilizes more medical care, including hospitalizations, emergency room visits, and long-term care. Dual-eligible beneficiaries comprise 21% of the Medicare population, and 31% of total Medicare costs, and 15% of the Medicaid population, and 39% of total Medicaid costs.^{116, 117} Before enactment of the Medicare prescription drug benefit, dual eligibles received their outpatient medications from Medicaid. The MMA changed that process; as of January 1, 2006, dual eligibles receive their prescription drugs primarily through the Medicare benefit (i.e., through PDPs and MA-PDs). This change affected approximately 16% of Medicaid beneficiaries and 42% of Medicaid prescription drug spending.¹¹⁸

Retail Community Pharmacy Reimbursement

Community pharmacy reimbursement typically includes both drug ingredient cost and dispensing fee components. Prior to PPACA federal guidelines, states reimbursed pharmacies for Medicaid prescriptions on the basis of an estimate of the ingredient cost of the drug, estimated acquisition cost (EAC), plus a dispensing fee. Costs for single-source drugs are typically reimbursed at a rate averaging AWP minus 14.3% or average of WAC plus 4%, plus a dispensing fee averaging \$5. In contrast, generic and multiple-source drugs are typically paid subject to a maximum allowable cost (MAC), and are subject to federal FULs applied in the aggregate for a particular drug. A minority of state Medicaid programs reimburse on the basis of Actual Acquisition Cost.¹¹⁹

As discussed in Section II, Payment Benchmarks, CMS proposed replacement of EAC with actual acquisition cost (AAC), and engaged Myers & Stauffer to provide state Medicaid agencies with acquisition costs and consumer purchase prices of covered outpatient drugs dispensed by pharmacies (not including specialty pharmacies), through a recurring pharmacy survey described on the Medicaid website titled ‘Survey of Retail Prices: Payment and Utilization Rates and Performance Rankings’ (see <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html>).

One survey objective is to collect data for calculation of National Average Retail Price (NARP), a monthly pricing database of actual drug prices from independent and chain pharmacies in the United States, including for cash paying customers, customers with commercial third party insurance, and Medicaid customers. A second survey objective is to collect data on the purchase prices of all Medicaid covered outpatient drugs by independent community pharmacies and chain pharmacies, for calculation of the National Average Drug Acquisition Cost (NADAC). CMS has proposed replacing the term “dispensing fee” with “professional dispensing fee” and requiring States to reconsider their dispensing fee methodologies when changing their payment for drug ingredient cost. Some states have performed pharmacy “cost to dispense” studies and have adjusted to survey-supported dispensing fees to provide pharmacies a dispensing fee that acknowledges their observed cost to dispense.

Rebates

The actual cost to Medicaid for prescription drugs is reduced by manufacturers’ rebates that are paid to the states and shared with the federal government. Medicaid programs receive a basic rebate from drug manufacturers for both brand-name and generic products. Between 2006 and 2010, the rebate program has saved Medicaid an average of about \$9 billion annually.¹⁹

In a study comparing 2009 Medicare Part D to Medicaid rebates, OIG found that Medicaid unit rebate amounts were three times greater than Part D unit rebate amounts at the median for the 100 brand-name drugs reviewed, and that consequently, Medicaid's net unit costs (i.e., pharmacy reimbursement minus rebates) were much lower than net unit costs under Part D. While Medicaid recovered 45% of spending on these drugs in manufacturer rebates, \$2.9 billion in rebates for \$6.4 billion in expenditures, Medicare Part D sponsors recovered 19%, or \$4.5 billion in rebates for \$24 billion in expenditures.¹²⁰

States can directly negotiate additional or "supplemental" Medicaid rebates, typically for high volume brand name drugs. Supplemental rebates have been as high as 25% above the basic federal rebate.¹²¹

In addition to basic rebates on branded drugs covered under Medicaid pharmacy benefit programs, the Federal Deficit Reduction Act of 2005 (P.L. 109-171) (DRA) requires all state Medicaid agencies to collect rebates from drug manufacturers for physician-administered drugs as a condition for receiving Federal matching funds. By June 2009, 73% of States responding to an OIG information request reported at least meeting this DRA requirement.²⁰

Prior to enactment of the PPACA on March 23, 2010, drugs dispensed by Medicaid MCOs were excluded from the basic rebate requirement. Section 2501(c) of PPACA required that drugs dispensed to beneficiaries enrolled in MA-PD plans be subject to the basic rebate requirement, and required that States must collect these rebates.¹⁹ The proposed rule, CMS 2345P, would, among other things, expand the definition of "States" in the Affordable Care Act to include the US territories of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa. If implemented, this rule would require manufacturers to extend Medicaid drug rebates to the territories and include applicable sales in AMP and best price calculations.¹²²

Each calendar quarter, for each unit of drug covered by a state Medicaid program, each manufacturer must pay either a basic rebate based on a percentage of the AMP or a rebate based on the best price available to wholesalers and other customers, with adjustment for price increases as reflected in the AMP since product launch that surpass the Consumer Price Index-Urban (CPI-U). The unit rebate amount (URA) is calculated as follows:¹²³

- Innovator Drugs—the greater of 23.1% of the Average Manufacturer Price (AMP) per unit or the difference between the AMP and the best price per unit and adjusted by the CPI-U based on launch date and current quarter AMP.
- Blood Clotting Factors—the greater of 17.1% of the AMP per unit or the difference between the AMP and the best price per unit and adjusted by the CPI-U based on launch date and current quarter AMP.

- Drugs Approved by FDA Exclusively for Pediatric Indications—the larger of 17.1% of the AMP per unit or the difference between the AMP and the best price per unit and adjusted by the CPI-U based on launch date and current quarter AMP.
- Line Extensions—For a drug that is a new formulation (a line extension) of a brand name drug that is an oral solid dosage form, the rebate is the amount computed as for an Innovator Drug or, if greater, the product of:
 - the AMP for the line extension drug,
 - the highest additional rebate for any strength of the original brand name drug, and
 - the total number of units of each dosage form and strength of the line extension drug.
- Cap on Total Rebate Amount for Innovator Drugs—The limit on the total rebate amount for each innovator drug is at 100% of the AMP.
- Non-innovator Drugs—13% of the AMP per unit.

■ ■ Private Purchasers

Private purchasers (also known as "payers" and "plan sponsors") provide the bulk of health insurance coverage in the United States for people younger than 65 years of age. In 2011, 63.9% and 197.3 million people were covered by private health insurance, of which 55.1% and 170.1 million were covered through employment or as dependents of those covered through employment. In that year, direct-purchase insurance was obtained by 9.8% and 30.2 million.¹²⁴ Exhibit III-9 provides a breakdown of health insurance coverage for the US population in 2010 and 2011, showing those people covered by more than one type of health insurance, and those covered by only a single type of health insurance, during the year.

Structure of Privately Sponsored Health Coverage

The Kaiser Family Foundation & Health Research and Educational Trust Employer Health Benefits 2012 annual survey demonstrated that 56% of workers were enrolled in PPOs, 19% in high-deductible health plans associated with savings options (HDHP/SOs), 16% in HMOs, 9% in point-of-sale (POS) plans, and 1% of covered workers were enrolled in conventional insurance plans.¹²⁵

Employer-sponsored coverage for beneficiaries enrolled in these plans may be fully insured or self-insured (also referred to as self-funded) and governed under the Employee Retirement and Income Security Act (ERISA) of 1974.¹²⁶ In a fully insured plan, the employer pays a per employee premium to the insurance company, which is then both responsible and at risk for provision of health coverage in accordance with policy provisions. In a self-

EXHIBIT III-9. COVERAGE BY TYPE OF HEALTH INSURANCE: 2010 AND 2011

(People as of March of the following year. For information on confidentiality protection, sampling error, nonsampling error, and definitions, see www.census.gov/apspd/techdoc/cps/cpsmar12.pdf)

Coverage type	2010 ¹	2011
Any private plan ²	64.0	63.9
Any private plan alone ³	52.5	*52.0
Employment-based ²	55.3	55.1
Employment-based alone ³	45.7	*45.1
Direct-purchase ²	9.9	9.8
Direct-purchase alone ³	3.7	3.6
Any government plan ²	31.2	*32.2
Any government plan alone ³	19.7	*20.4
Medicare ²	14.6	*15.2
Medicare alone ³	4.7	*4.9
Medicaid ²	15.8	*16.5
Medicaid alone ³	11.1	*11.5
Military health care ^{2,4}	4.2	*4.4
Military health care alone ^{3,4}	1.3	1.3
Uninsured	16.3	*15.7

* Change between the 2010 and 2011 estimates are statistically different from zero at the 90 percent confidence level.

¹ Implementation of Census 2010-based population controls.

² The estimates by type of coverage are *not* mutually exclusive; people can be covered by more than one type of health insurance during the year.

³ The estimates by type of coverage are mutually exclusive; people did not have any other type of health insurance during the year.

⁴ Military health care includes Tricare and CHAMPVA (Civilian Health and Medical Program of the Department of Veteran Affairs), as well as care provided by the Department of Veterans Affairs and the military.

Source: U.S. Census Bureau, Current Population Survey, 2011 and 2012 Annual Social and Economic Supplements.

Source: *Income, Poverty and Health Insurance Coverage in the U.S.: 2011*. U.S. Census Bureau, September 2012.¹²⁴

insured plan, the employer acts as its own insurer, but typically with stop-loss reinsurance for unexpectedly high per person and/or aggregate medical costs, with final authority for establishing coverage policies, and for paying providers directly or through a third-party administrator for provision of health products and services.

In 2011, 58.5% of workers with health coverage were in self-insured plans, ranging by state from 30.5% to 73.8%. Self-insurance varies by firm size, so that in 2011 68.5% of workers in firms with 50 or more employees were in self-insured plans, while only 10.8% of workers in firms with fewer than

50 employees were in self-insured plans. Self-insurance among workers in firms with 100-999 employees is 35%, and is 86.3% among workers in firms with over 1,000 employees. Firms that do not self-insure are subject to state-mandated benefits (the most popular mandates are: mammography screening, maternity minimum stay, breast reconstruction, mental health parity, and alcohol and substance abuse).¹²⁷ ERISA exempts firms that self-insure from these coverage mandates. There is concern that PPACA implementation in January 2014 will result in an increasing number of smaller employers choosing to self-insure as a way to avoid PPACA-related mandates.¹²⁸

Benefit Design

Private purchasers use benefit design features to affect payment for all forms of pharmaceuticals. The Takeda 2012–2013 Prescription Drug Benefit Cost and Plan Design Report provides detail regarding popular pharmacy benefit designs.³⁸ Benefit design can be used to determine payment levels in several ways:

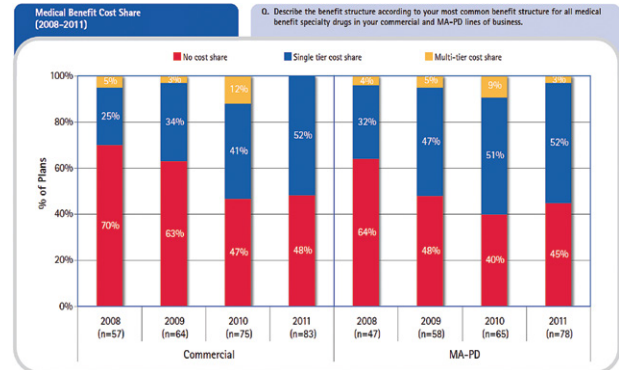
- Under which part of the insurance benefit (e.g., medical or pharmacy) the drug will be paid and, within these broad categories, whether it will be paid on a fee-for-service basis or bundled in a subcontracted provider’s responsibility and payment.
- If paid on a fee-for-service basis, whether the prescription drug will be “carved-in” (provided directly by the insurer) or “carved-out” (provision contracted to a designated vendor).
- Whether the benefit will be subject to requirements such as drug formulary, formulary tiers, prior authorization, step therapy, drug-specific coverage policies, maximum dispensed amount (quantity or days supply), and/or mandatory mail order or mandatory specialty pharmacy.
- The type and amount of the patient’s cost-sharing responsibility, and the circumstances under which the cost share will be a coinsurance percentage, a copayment dollar amount, an amount equal to the charged amount that exceeds a maximum reference price that the plan will pay, or 100% of the authorized product cost.
- Whether there is a pharmacy deductible and/or a maximum annual payable amount (i.e., stop-loss for the member or for the drug plan), separately from any deductible or maximum annual payable amount that may apply to other specific portions of the health benefit.

Drugs Assigned to the Medical Benefit vs. Pharmacy Benefit

Unlike the formulary tier-based prescription drug copayment structure typical of pharmacy benefits, it is common for drugs covered under the medical benefit—usually considered specialty pharmaceuticals—to carry zero cost share in addition to and separate from the cost share due for the office visit itself. This is demonstrated in survey results as shown in Exhibit III-10, where ‘multi-tier cost share’ refers to drugs assigned to preferred or to non-preferred formulary copay tiers.

Unless administered through pharmacy benefit adjudication systems, drugs covered under the medical benefit typically lack the benefits language or claims adjudication systems to support preferred or non-preferred formulary tier placement—although payer coverage policies may condition payment of a particular therapy on patient medical status or failure on

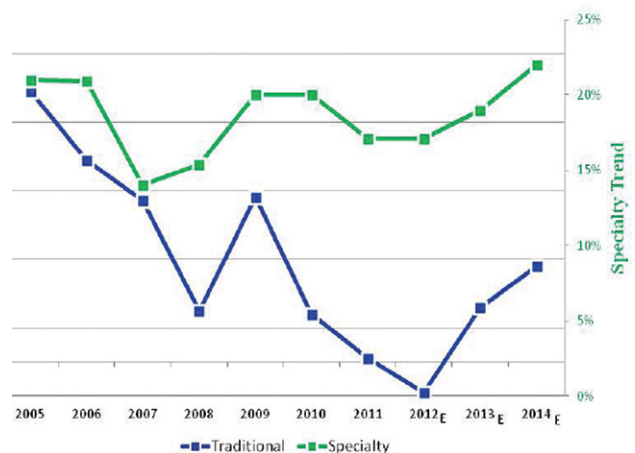
EXHIBIT III-10. MEDICAL BENEFIT COST SHARING FOR SPECIALTY DRUGS



Source: EMD Serono Specialty Digest 8th Edition 2012.¹²⁹

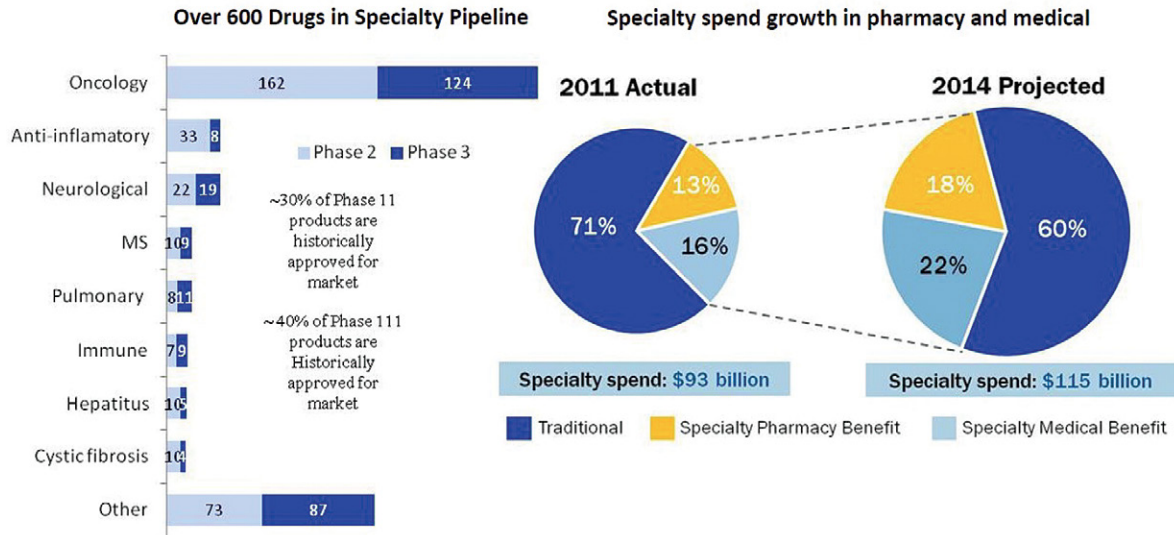
alternative therapies. Thus it is more difficult for the payer to channel prescribing of drugs covered under the medical benefit to particular preferred products, and to earn meaningful product discounts from rebates. This has become an important payer concern in recent years due to the high year-over-year growth for specialty drug spend (see Exhibit III-11).^{130, 131}

EXHIBIT III-11. PHARMACY COST TRENDS



Source: Express Scripts presentation. JPMorgan 2013 Healthcare Conference. Available at <http://phx.corporate-ir.net/phoenix.zhtml?c=69641&p=irol-presentations>. Accessed January 26, 2013.

EXHIBIT III-12. SPECIALTY DRUGS IN THE DRUG DEVELOPMENT PIPELINE, AND PROJECTED IMPACT OF SPECIALTY DRUGS ON DRUG SPEND



Source: Express Scripts presentation. JPMorgan 2013 Healthcare Conference.

Specialty drugs have become of increasing concern to payers in light of the robust pipeline of biotechnology products in clinical trials that are expected to drive continued high growth in specialty drug spend (see Exhibit III-12).¹³¹

To address the problem of increasing exposure to specialty drug costs and inadequate ability to control these costs, some payers have applied pharmacy benefit systems and/or distribution channels—such as mandatory specialty pharmacy dispensing—to medical benefit drugs. Exhibit III-13 shows that in 2011, 5% of plans assigned office administered drugs—which are typically assigned to the medical benefit—to the pharmacy benefit, in which setting pharmacy benefits language and claims processing systems may be applied.¹²⁹

Use of Formularies

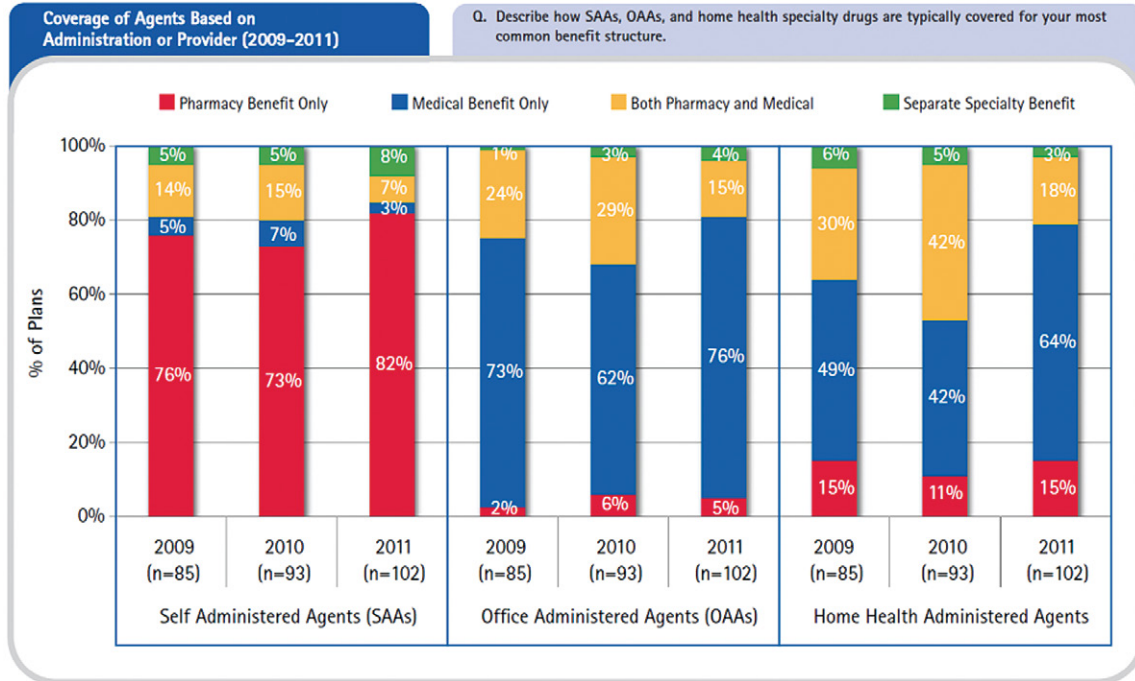
A formulary is a list of drugs in a pharmacy benefit that are designated as preferred, non-preferred or not covered (explicitly or by omission from the list) by the pharmacy and therapeutics (P&T) committee of the health plan or PBM, based on effectiveness, safety, and cost considerations. Many health plans have tiered formularies, with drugs categorized by copayment or coinsurance levels, in which non-preferred drugs may be covered but with a higher cost-share for members. Member cost-share at the point of service is a fixed-dollar copayment or a percentage of drug cost (i.e., coinsurance). These copayment and coinsurance

levels are intended to influence utilization, typically to encourage a shift from expensive brand-name non-preferred drugs to less expensive alternatives, which may be generic equivalents or therapeutic equivalents. Objectives of channeling physician prescribing and patient preference toward drug formulary priorities include reduced pharmacy benefit cost and lower year over year cost trend. Increased member cost-share at the point of service also serves to reduce payer share of pharmacy benefit cost.

From health plan and PBM perspectives, formularies are used as tools to manage care and cost. By choosing to place a drug on a multi-tier formulary, the PBM or health plan generates leverage with the manufacturer of that drug and with manufacturers of drugs that may be therapeutically equivalent to it. By creating the ability to steer utilization toward a particular drug that has clinical equivalence or preference to others in the class, the plan can offer a drug manufacturer a higher market share in exchange for a lower purchase price or a higher rebate that also achieves a lower net price. A formulary with fewer clinically therapeutic alternatives in a preferred tier or larger patient-based financial incentives will increase this leverage because this increases manufacturer’s drug market share opportunity.

Formularies, formulary tiering, tier-based copayments, and coinsurance levels are some of the most important benefit design features in use today to customize payment and determine patient

EXHIBIT III-13. MEDICAL AND PHARMACY BENEFIT COVERAGE BY DRUG ADMINISTRATION TYPE



Source: EMD Serono Specialty Digest 8th Edition 2012.¹²⁹

financial responsibilities for specific drugs. Although drug formularies impact the contracted pharmacies within a purchaser’s administration, pharmacies are typically not involved in decision-making regarding formulary content or copayment amounts and generally do not share in the economic rewards of these programs.

Typically, formularies have 3 or 4 cost-share tiers, with generic drugs often placed in the first tier, preferred brand drugs placed in a second tier, and non-preferred brand drugs placed in a third tier. In a formulary with a fourth tier, that tier is usually reserved for expensive injectable and specialty drugs and has the highest cost-share (i.e., copayment amount or coinsurance percentage). A minority of plans use five cost-share tiers, in which there are preferred and non-preferred tiers for both multiple source generic drugs and branded drugs, plus a tier for specialty drugs.³⁸

Patient cost sharing has steadily increased since 2000, primarily for more expensive drugs. Exhibit III-14 shows average patient copayment amounts in commercial plans.

Beneficiary cost sharing in the Medicare Part D setting generally follows a similar pattern as for commercial plans (see Exhibit III-15). In 2012, the vast majority of Part D plans had a

tiered cost-sharing structure with incentives for enrollees to use less expensive generic and preferred brand-name drugs. Only 9% of PDPs (representing 5% of enrollment) and 2% of MA-PD plans (representing 1% of enrollment) did not use a formulary with coverage tiers. About 49% of PDPs and 37% of MA-PDs used formularies with five cost-sharing tiers, which have preferred and non-preferred tiers for generic drugs and for brand drugs, plus a specialty drug tier; and 42% of PDPs and 59% of MA-PDs continued to use formularies with four cost-sharing tiers. About 53% of PDPs charged a deductible in 2012, and most of these used the standard deductible allowed by law (\$320 in 2012). Only 11% of MA-PDs used a drug deductible. Most PDPs used a flat copayment for the generic drug tier, and some used a flat copayment for preferred brand drugs. Of PDPs with a non-preferred brand drug tier, 30% charged a coinsurance rate for those drugs. PDPs and MA-PD plans had similar cost-sharing. Median cost sharing for a 30-day supply of “non-preferred” brand-name drugs was \$92, and cost sharing for “preferred” brand drugs was \$41. Median cost sharing for generic drugs was \$5. The median cost sharing for plans with two generic tiers was \$4 for the preferred generic tier and \$8 for the non-preferred tier.

EXHIBIT III-14. PRESCRIPTION DRUG COST SHARING AMONG COVERED WORKERS

Among Covered Workers with Three, Four, or More Tiers of Prescription Cost Sharing, Average Copayments and Average Coinsurance by Drug Type, 2000–2012													
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Average Copayments													
First-Tier Drugs, Often Called Generic	\$8	\$8	\$9	\$9*	\$10*	\$10	\$11*	\$11	\$10	\$10	\$11	\$10	\$10
Second-Tier Drugs, Often Called Preferred	\$15	\$16*	\$18*	\$20*	\$22*	\$23*	\$25*	\$25	\$26	\$27	\$28*	\$29	\$29
Third-Tier Drugs, Often Called Nonpreferred	\$29	\$28	\$32*	\$35*	\$38*	\$40*	\$43*	\$43	\$46*	\$46	\$49*	\$49	\$51
Fourth-Tier Drugs	^	^	^	^	\$59	\$74	\$59	\$71*	\$75	\$85	\$89	\$91	\$79
Average Coinsurance													
First-Tier Drugs, Often Called Generic	18%	18%	18%	18%	18%	19%	19%	21%	21%	20%	17%	18%	20%*
Second-Tier Drugs, Often Called Preferred	NSD	23%	24%	23%	25%	27%	26%	26%	25%	26%	25%	25%	26%
Third-Tier Drugs, Often Called Nonpreferred	28%	33%	40%	34%*	34%	38%	38%	40%	38%	37%	38%	39%	39%
Fourth-Tier Drugs	^	^	^	^	30%	43%*	42%	36%	28%	31%	36%	29%	32%

SOURCE:
Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2000–2012.

* Estimate is statistically different from estimate for the previous year shown (p<.05).
^ Fourth-tier drug copayment or coinsurance information was not obtained prior to 2004.
NSD: Not Sufficient Data.

Traditional and Transparent Pricing

In recent years, some PBMs have emphasized transparency in customer relations, including “transparent” pricing in their payer contract offers.¹³³

PBM traditional pricing for retail and mail-order pharmacy is typically offered on the basis of the AWP benchmark for single-source branded pharmaceuticals, and proprietary MAC on multiple-source pharmaceuticals. Contracts may guarantee the overall value of the MAC as a percentage AWP discount, although this guarantee is difficult to validate because MAC details typically are not shared with PBM clients. Some contracts guarantee the AWP-discount value of all multiple-source products, whether or not they are on the MAC list, in the aggregate. A dispensing fee, in addition to the ingredient cost, typically applies.

In contrast, PBM transparent pricing for retail and mail-order pharmacy specifies that the actual PBM payments to pharmacy providers are passed through to the payer without markup or alteration. This form of pricing generally does not specify a particular AWP-discount price that will be charged to the payer for

single-source branded pharmaceuticals, but may guarantee the overall claims value in terms of an average AWP discount. The reason for the absence of a specified AWP discount is that PBM pharmacy network contracts are negotiated individually, may vary among pharmacy providers and are proprietary. Plans are typically charged a higher administrative (PMPM or per claim) fee in a transparent model to offset lost subsidies in traditional models.

Specialty pharmaceuticals are often priced differently to payers. Individual specialty pharmaceuticals may be listed in the contract, priced on an AWP-discount basis that may differ depending on whether the payer opts for an exclusive provider arrangement with the specialty pharmacy, or for an open provider model in which the patient also may obtain specialty pharmaceuticals from network retail pharmacies. A MAC may apply for multiple-source specialty pharmaceuticals. Specialty pharmaceuticals not individually priced in a payer contract may be subject to a standard AWP discounted price. A dispensing fee may apply.

Contracts with pharmacy providers typically include “lower of” provisions in which the PBM or plan sponsor pays no more than

EXHIBIT III-15. COST SHARING FOR MEDICARE PART D PLANS 2006–2012, AND EMPLOYER-SPONSORED PLANS, 2012

FORMULARY TIER	PART D PLAN TYPE	PART D COST SHARING							EMPLOYER PLANS
		2006	2007	2008	2009	2010	2011	2012	2012
Generic	PDP	\$5	\$5	\$5	\$7	\$7	\$7	\$5	\$10
	MA-PD	\$5	\$5	\$5	\$5	\$6	\$6	\$6	
Preferred brand	PDP	\$28	\$28	\$30	\$37	\$42	\$42	\$41	\$29
	MA-PD	\$26.70	\$29	\$30	\$30	\$39	\$40	\$42	
Non-preferred brand	PDP	\$55	\$60	\$71.50	\$74.75	\$76.50	\$78	\$92	\$51
	MA-PD	\$55	\$60	\$60	\$60	\$79	\$80	\$84	
Specialty	PDP	25%	30%	30%	33%	30%	30%	29%	32%
	MA-PD	25%	25%	25%	33%	33%	33%	33%	

NOTES: Part D cost-sharing amounts are medians; employer plan cost-sharing amounts are means. Part D plan estimates weighted by enrollment in each year; analysis excludes generic/brand plans, plans with coinsurance for regular tiers, and plans with flat copayments for specialty tiers.

SOURCE: Georgetown/NORC analysis of data from CMS for MedPAC and the Kaiser Family Foundation; data on employer plans from Kaiser/HRET Employer Health Benefits Survey, 2012.



Source: Analysis of Medicare prescription drug plans in 2012 and key trends since 2006. Hoadley J, Summer L, Cubanski J, Neuman T. Kaiser Family Foundation. September 2012. Available at <http://www.kff.org/medicare/upload/8357.pdf>. Accessed January 23, 2013.

what would be paid by a pharmacy customer paying out-of-pocket without pharmacy benefit coverage or under other specified conditions. “Lower of” provisions may include: Usual and Customary, Submitted Amount, Negotiated Price Formula, Usual Customary and Reasonable, and State Fee Schedule (for worker’s compensation programs). Contractual “lower of” provisions have become more important in recent years as a result of the community pharmacy “generic price war”¹³⁴ However “lower of” provisions would not apply in the case of a community pharmacy generic program available only to those subscribed to the pharmacy’s ‘generics club’, a common requirement, because prices available to specified groups are not the pharmacy’s ‘usual and customary’ prices.¹³⁴

Class of Trade

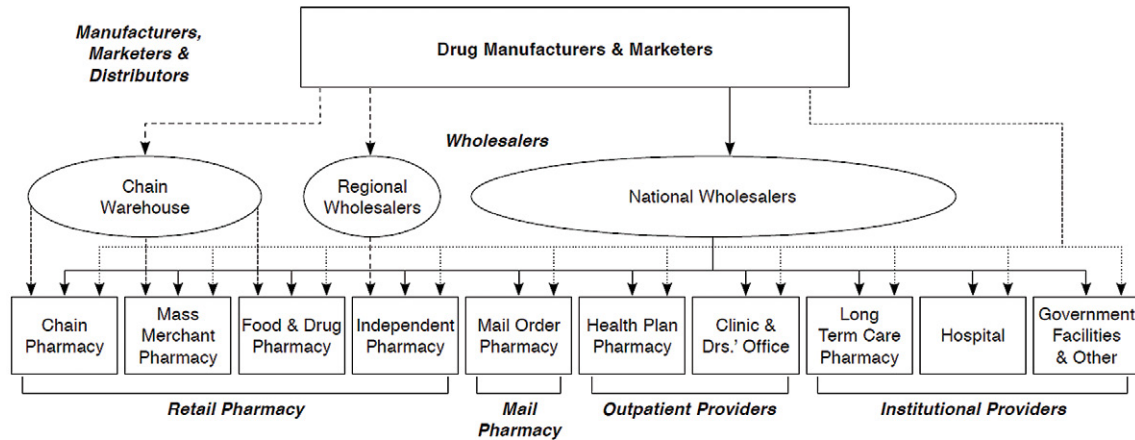
Pharmaceutical manufacturers may, at their discretion, group their customers by class of trade (COT) and offer certain price concessions to some COTs and not to others. For this reason,

a purchaser’s net purchase cost for prescription drugs is often a function of manufacturer-offered price concessions, within the bounds of what manufacturer’s internal and confidential policy states may be offered to purchaser’s COT, applied to the list price. Exhibit III-16 shows one view of COTs, however, each pharmaceutical manufacturer may categorize its customers differently.¹³⁵ For this reason a drug in a competitive therapeutic category that is sold to a physician office for patient administration may yield a different price, net of price concessions, compared to the same drug when purchased by a specialty pharmacy.

Prescription Drug Rebates

Although health plans and PBMs typically do not take possession of drugs, drug manufacturers pay rebates, typically on a calendar quarterly basis directly to them based on performance with volume, share, formulary placement, and other contractual terms.

EXHIBIT III-16. EXAMPLE OF PHARMACEUTICAL CLASSES OF TRADE



The link between drug formulary tiers and manufacturer rebates is important in understanding the true net cost of a drug. Rebates may be based on enrollee utilization of a specific drug or based on the market share of that drug compared with other drugs in a therapeutic class or mutually defined list of products. In some cases, rebates are based on changes in the share of drugs rather than the absolute share. Rebates also may be based on favored inclusion of a drug on a restrictive formulary. Availability of a rebate provides the purchaser (or its contracted intermediary, such as a PBM or health plan) with an incentive to put a manufacturer's branded drug on the second (preferred brand) tier rather than the third (non-preferred) or higher copayment tier. The purchaser also may have an incentive, negotiated or operational, to limit the number of other branded products in the same therapeutic class assigned to the preferred copayment tier to increase the unit rebate for one preferred drug.

More generous rebates are often available for branded drugs that treat conditions for which an alternative therapeutically equivalent generic or brand-name treatment is available. Large rebate percentages are less likely to be offered for new drugs perceived to be without therapeutically interchangeable alternatives and for breakthrough drugs, because manufacturers perceive no need to negotiate prices to obtain favorable formulary status for these products. Rebates are also not typically offered for generic drugs or for multiple-source brand-name drugs when generics have been available for a long period of time.

The extent to which drug manufacturer rebates are shared among PBM, health plan, and purchaser is a matter of considerable attention and debate. As intermediaries between

employers or health plans and pharmacy providers, PBMs vary in the extent to which rebates are shared with client purchasers. The amount shared depends on negotiation of all variables in the contract between the employer and PBM (or health plan), including variables such as retail pharmacy network discounts and administrative fees. For example, an employer may desire to pay a higher administrative fee and receive more rebates or pay a lower administrative fee and a lower share of rebates. A manufacturer drug rebate may be shared on the basis of a guaranteed fixed dollar amount per retail or mail order prescription, rather than on the basis of a percentage of rebate collected, disassociating the amount paid from the amount of rebate actually collected (and thus limiting the scope of a subsequent audit). Rebates may also be passed through on a 100% basis, in exchange for higher administrative fees.

Furthermore, there may be other fees paid by the pharmaceutical manufacturer which are not "rebates" but which are attributable to the drug formulary and its management. These may include: Administration Fees, PMPM flat fees, Clinical Program Services fees, and Product Listing fees.

Pharmaceutical manufacturer rebates and other price concessions to health plans and PBMs have no direct and immediate impact on reimbursement to contracted pharmacies. However, in an AMP- or ASP-benchmarked system in which payment is a markup on one of these benchmarks, rebates and other price reductions that lower the overall reportable selling price also ultimately lower the pharmacy's allowable cost and net margin of profit (assuming that no change occurs in pharmacy acquisition cost and the dispensing fee remains constant).

Importation and Reimportation of Pharmaceuticals

According to a CBO report, “average prices for patented drugs in other industrialized countries are 35% to 55% lower than in the United States.” The U.S. government reportedly does not consistently stop individuals from purchasing drug products abroad. Internet sales and personal importation through physical travel to Canada totaled about \$700 million in sales in 2003, or 0.3% of total U.S. prescription sales, and about the same dollar value of prescription drugs is estimated to have entered the United States from the rest of the world.

However, “while an individual can fill a prescription in another country and realize savings reflecting the full difference in price, the same would not be true for the health care system as a whole.”¹³⁶ Importation of a prescription drug (or reimportation, if the prescription drug is manufactured in the United States) is generally not lawful for individuals or commercial entities such as pharmacies or wholesalers.¹³⁷ Section 535 of P.L. 109-295 (enacted in 2006) allows U.S. residents to transport up to a

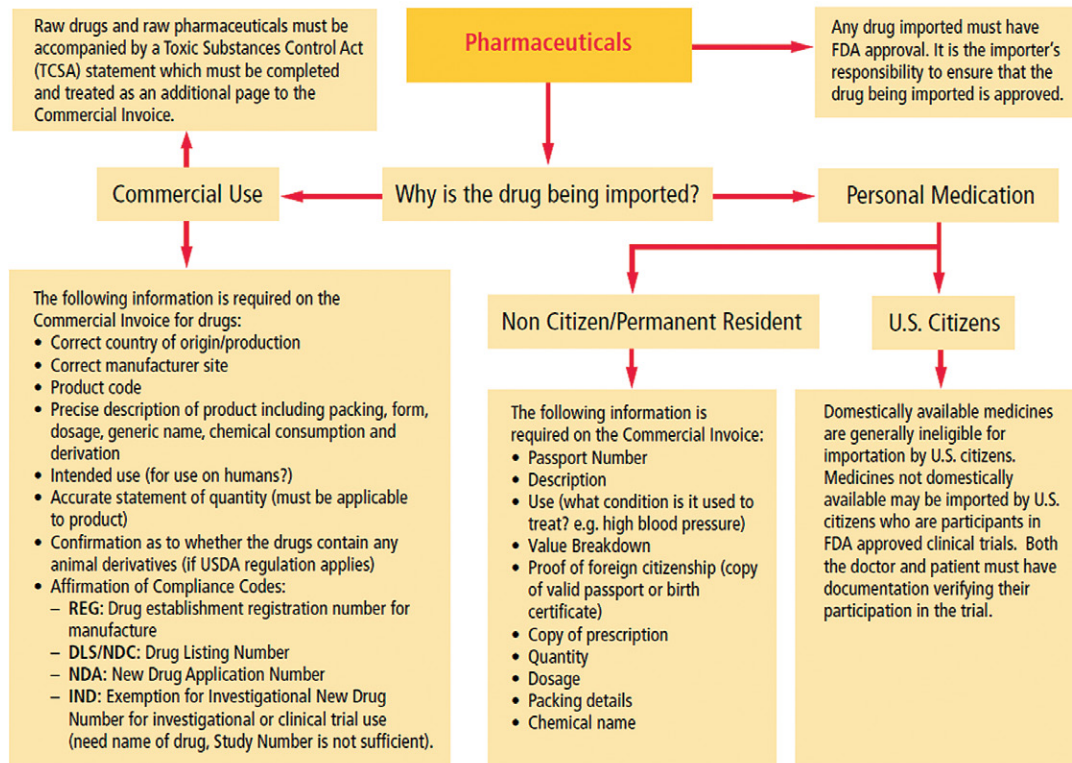
90-day supply of qualified drugs from Canada to the United States, excepting controlled substances and biological products.¹³⁸ Exhibit III-17 shows one shipper’s customer guidance with respect to drug importation.¹³⁹

Because of the drug price difference internationally, some people have used drug importation to reduce their prescription drug cost. Yet, safety considerations exist. Key findings of the DHHS Task Force on Drug Importation are as follows: “There are significant risks associated with the way individuals are currently importing drugs; and it would be extraordinarily difficult and costly for ‘personal’ importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs.”¹⁴⁰

Patient Expenditures for Pharmaceuticals

For costs paid by or on behalf of a typical family of four covered by an employer-sponsored PPO, one medical index estimates that the actuarial value of annual family pharmacy cost in this scenario is \$3,056 of a total annual medical cost of \$20,728.²⁷

EXHIBIT III-17. SHIPPER’S CUSTOMER GUIDANCE FOR PHARMACEUTICALS IMPORTATION



Medicare beneficiary cost-share for prescriptions was lowered subsequent to the Part D benefit, but remained significant, particularly for beneficiaries who reached the benefit design coverage gap (the “doughnut hole”).¹⁴¹ In one analysis, Part D reduced out-of-pocket spending 13.4% among those without prior coverage, and 15.9% among those with \$150 quarterly caps.¹⁴² PPACA further reduces Medicare beneficiary cost-sharing over several years by filling the Part D doughnut hole (see Section III, Payers and Payment Methods, The Part D Coverage Gap).

People without prescription drug insurance or with inadequate coverage may be eligible for prescription drug discount cards, offered by county government, pharmacy benefit managers and community pharmacies. Discount cards may be honored only at certain community pharmacies, may reduce the purchase price of all pharmaceuticals purchased or only of generics, and may be fee-based or free to those meeting eligibility criteria.^{143,144,145} Another alternative is copay assistance, through copay coupons and copay cards offered by non-profit organizations and pharmaceutical manufacturers, as discussed in the next section.

Drug Copay Coupons and Copay Cards

Pharmacy benefit programs typically include tiered drug formularies which specify higher cost-share for non-preferred generic, brand and specialty drugs than for preferred generic and brand drugs. Copay coupons and copay cards reduce or eliminate patient cost-share for the first (or for the first several) prescriptions, and thereby encourage the use of non-preferred drugs. Although copay assistance may end after one or more prescriptions, the situation for non-preferred drugs intended for chronic use is that patients will often continue taking the non-preferred drug on a long-term basis, thereby raising both third party payer net cost and beneficiary out-of pocket cost-share. In so doing, copay cards thwart payers’ efforts to manage drug spend through the drug formulary process. According to a recent study, by reducing the use of generics and more affordable brands, copay coupons could increase ten-year prescription costs by \$32 billion.¹⁴⁶

The Office of the Inspector General has scheduled a review of copay cards for fiscal year 2014 (the OIG report is catalogued as OIE 05-12-00460), writing in its workplan “We will identify safeguards pharmaceutical manufacturers have in place to ensure that beneficiaries do not use copayment coupons to obtain prescription drugs paid for by Medicare Part D. The use of copay coupons in Federal health programs implicates the anti-kickback statute. Coupons may create an incentive for beneficiaries to choose more expensive brand-name drugs over lower-cost generic drugs. A recent survey suggests that beneficiaries are using copay coupons to obtain specific brand-name prescription drugs, causing Medicare to pay more than necessary when less costly versions of the same drugs are available.”¹⁴⁷

An alternate view expressed by some is that the discount coupons and cards provide price concession directly to the consumer rather than to the insurance plan or plan administrator/ PBM. If the plan received the price concession it would be termed a “rebate” and included in a variety of benchmark price calculations. But when the cost benefit is “passed on to the consumer” it is excluded from calculation.

Copay assistance can also be provided in certain circumstances by manufacturers and not-for-profit foundations based upon a patient’s economic need. Generally those programs are seen with high cost specialty drugs for debilitating or life threatening diseases, where the drug’s cost sharing would prevent an insured patient from accessing the treatment.

Relationship of Provider to Payment Method

The payment method varies by provider type in the private sector as it does in the public sector. However, in the private sector, payment methods are far more variable. Because payment methods are held in confidence by the contracting parties, little is known publicly about individual payment arrangements, how these arrangements compare across provider types, or trends in these arrangements over time.

Community Pharmacy

In the commercial market, community pharmacy is generally paid by a third party payer for the ingredient cost component based on a percentage discount or markup on a benchmark, typically AWP or WAC, respectively, for single-source brand drugs. For multiple-source drugs, payment is usually subject to a health plan- or PBM- defined MAC price list. A negotiated fee is paid for professional services including dispensing. Some purchasers make an additional payment to the community pharmacy for work expended in gaining substitution with a preferred product when a non-preferred product was prescribed.

This product-based reimbursement formula in community pharmacy is expressed as an ingredient cost calculation plus dispensing fee, such as the following, subject to ‘lower of’ provisions, i.e., against pharmacy usual & customary pricing:

- AWP – X% + \$x.xx
- WAC + X% + \$x.xx
- MAC + \$x.xx (for multiple-source drugs)
- Usual and Customary

Exhibit III-18 shows average community pharmacy reimbursement discounts from AWP, based on a May–June 2012 survey of 424 large and small employers.³⁸ Dispensing fees shown in Exhibit III-18 survey results are not representative of pharmacists’ actual dispensing costs, because a large fraction of these costs are typically subsumed into the margin generated by

EXHIBIT III-18. PHARMACY DISCOUNTS AND DISPENSING FEES BY PHARMACY CHANNEL

Pharmacy Discounts and Dispensing Fees by Pharmacy Channel		
	Average AWP Discount	Average Dispensing Fee
Retail 30		
Generics	68.2%	\$1.66
Brands	16.1%	\$1.68
Retail 90		
Generics	NA	\$1.61
Brands	17.1%	\$1.35
Mail		
Generics	62.2%	\$0.74
Brands	23.1%	\$0.74
Specialty		
Brands	16.3%	\$1.10

Source: The Pharmacy Benefit Management Institute. 2012-2013 Prescription drug benefit cost and plan design report. Takeda Pharmaceuticals North America, Inc. August 2012. Available at: <http://www.pbmi.com/BenefitDesign.asp>. Accessed January 13, 2013.

the drug ingredient reimbursement formula. Identifying the actual cost of dispensing has become important for State Medicaid programs wishing to replace pharmacy reimbursement based on estimated acquisition cost of drug ingredients which includes these margins, with actual acquisition cost of drug ingredients which does not include these margins.¹⁴⁸

Providers of Specialty Injectables. Drug payment for specialty injectables, as well as beneficiary cost-share responsibility for these products, depends on the benefit under which the injectable is covered as well as the provider dispensing or administering the product. Specialty injectables, including self-administered and office-administered injectables, may be included in a payer’s pharmacy benefit and/or covered through the medical benefit. Purchasers contract with several types of specialty injectable providers. For the medical benefit, providers typically include office-based physicians, outpatient hospital, and home health agencies, home infusion pharmacies and specialty pharmacies. Pharmaceutical benefit providers typically include community, mail-order, and specialty pharmacies.

Whether payment for provider-administered specialty injectables is bundled (for example, DRGs for injectables administered in the hospital inpatient setting, and prospective payment for injectables administered in dialysis clinics) or made

on a fee-for-service basis, depends on the site of care where the specialty injectable is administered. Exhibit III-19 shows the variation in site of care for a sampling of injectables, based on health plan paid claims data from a large proprietary data set.¹⁴⁹

Shown in Exhibits III-20 and III-21 are survey results of the average commercial health plan ASP plus and AWP minus payment formulas for pharmaceuticals administered in physician offices and clinics. For patients with private coverage, ASP+18% is the weighted mean reimbursement for physicians reimbursed on an ASP basis, and AWP-15% is the most common reimbursement on an AWP basis.

As shown in Exhibit III-22, a significant portion of the commercial marketplace has shifted from AWP-based reimbursement to ASP-based reimbursement.

As shown in Exhibit III-23, an increasing percentage of infused drugs administered in the physician office is supplied by a specialty pharmacy, and billed by the specialty pharmacy to the third party payer. This pattern is occurring despite that, per the ICORE Medical Pharmacy & Oncology Trend Report, “specialty pharmacy acquisition costs are 17% higher on a weighted average basis than in the provider’s office”.¹⁴⁹

Hospital Inpatient and Outpatient. Because per diem and prospective payment are the most frequently used payment

III. PAYERS AND PAYMENT METHODS

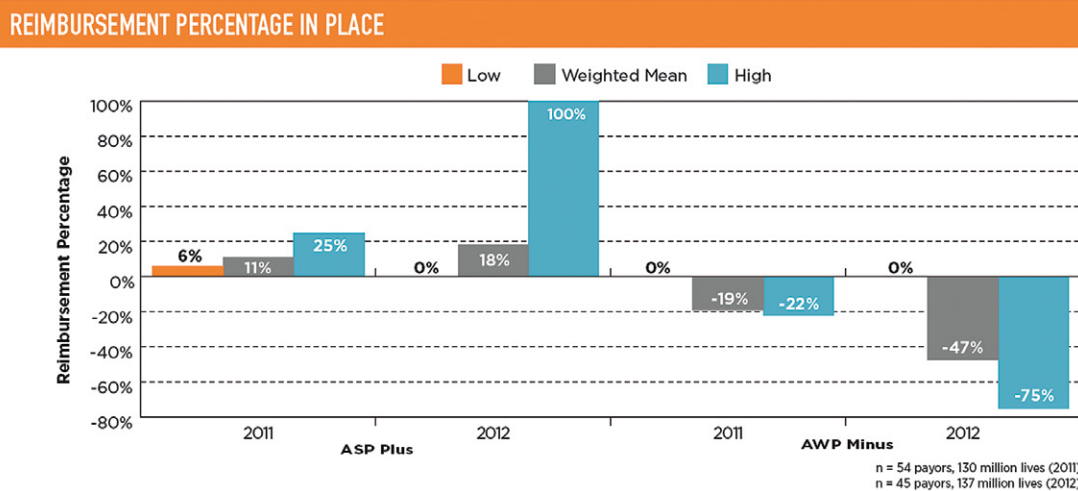
EXHIBIT III-19. DRUG UTILIZATION PER 1 MILLION HEALTH PLAN LIVES BY SITE OF SERVICE

BRAND NAME	RANKING	PERCENT OF CLAIM											
		HOSPITAL			HOME INFUSION/SPP			OTHER (ESRD, CLINICS, ETC.)			MEDICAL OFFICE		
		2009	2010	2011	2009	2010	2011	2009	2010	2011	2009	2010	2011
Remicade	1	23%	20%	23%	12%	8%	7%	1%	0%	0%	64%	71%	69%
Neulasta	2	24%	30%	31%	2%	1%	1%	1%	1%	2%	72%	68%	67%
Avastin	3	20%	18%	18%	3%	2%	1%	1%	1%	1%	76%	79%	81%
Rituxan	4	25%	32%	36%	2%	1%	1%	1%	1%	1%	71%	66%	63%
Lucentis	5	1%	0%	1%	8%	4%	3%	0%	0%	0%	91%	96%	95%
Herceptin	6	23%	28%	36%	1%	0%	0%	2%	2%	1%	74%	70%	63%
Eloxatin	7	28%	29%	38%	2%	0%	0%	2%	1%	2%	68%	69%	59%
Gammagard	8	22%	19%	18%	63%	66%	65%	1%	0%	0%	14%	15%	17%
Taxotere	9	22%	28%	31%	2%	1%	0%	1%	1%	1%	75%	71%	68%
Alimta	10	30%	38%	42%	2%	0%	0%	2%	2%	2%	66%	60%	56%

*\$ per claim drop was a result of shift in sight of service, off-label use and the FDA decision to revoke the approval of the breast cancer indication for Avastin.

Source: Medical Pharmacy & Oncology Trend Report. Third Edition, 2012. Available at <http://www.icorehealthcare.com/icore-resources/trend-report.aspx>. Used with permission.

EXHIBIT III-20. PRIVATE SECTOR ASP-BASED PHYSICIAN REIMBURSEMENT FOR OFFICE-ADMINISTERED INFUSIBLE AND INJECTABLE DRUGS



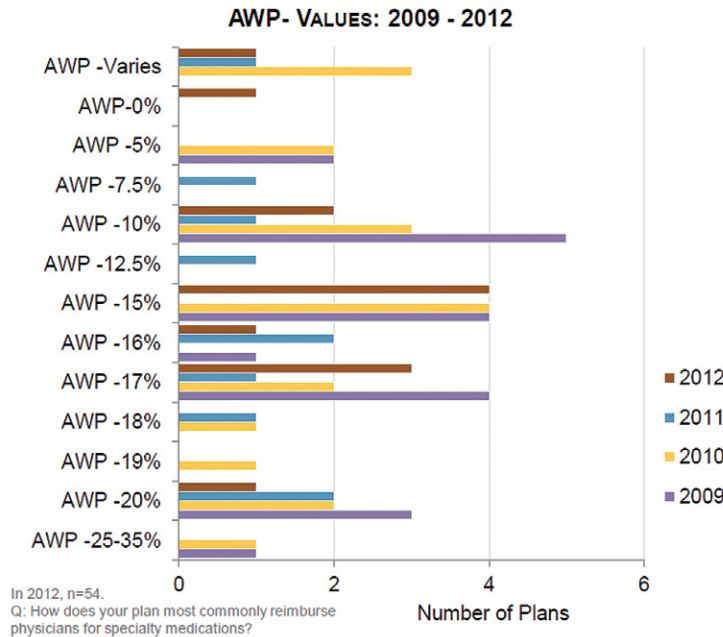
Source: Medical Pharmacy & Oncology Trend Report. Third Edition, 2012. Available at <http://www.icorehealthcare.com/icore-resources/trend-report.aspx>. Used with permission.

methods in these settings, separate payment for drugs in the inpatient hospital setting seldom occurs. However, most drugs administered in a hospital outpatient setting are reimbursed separately if they exceed a predetermined cost threshold, which is negotiated between the hospital and the payer.

Physician Office Drugs. Unless the physician has entered into a capitation or a bundled-payment arrangement, most physician-administered drugs are reimbursed separately. The business failure of several physician practice management organizations (organizations that own or manage physician practices) in the

EXHIBIT III-21. PRIVATE SECTOR AWP-BASED PHYSICIAN REIMBURSEMENT FOR OFFICE-ADMINISTERED INFUSIBLE AND INJECTABLE DRUGS

AWP - 15% Is Most Common AWP-based Reimbursement Value



VI-3

Specialty Pharmaceuticals Service ©2012



Source: Specialty Pharmacy Service. Health Industries Research Center. Available (by subscription) at <http://www.hirc.com/sps/summary>. Used with permission. Accessed February 7, 2013.

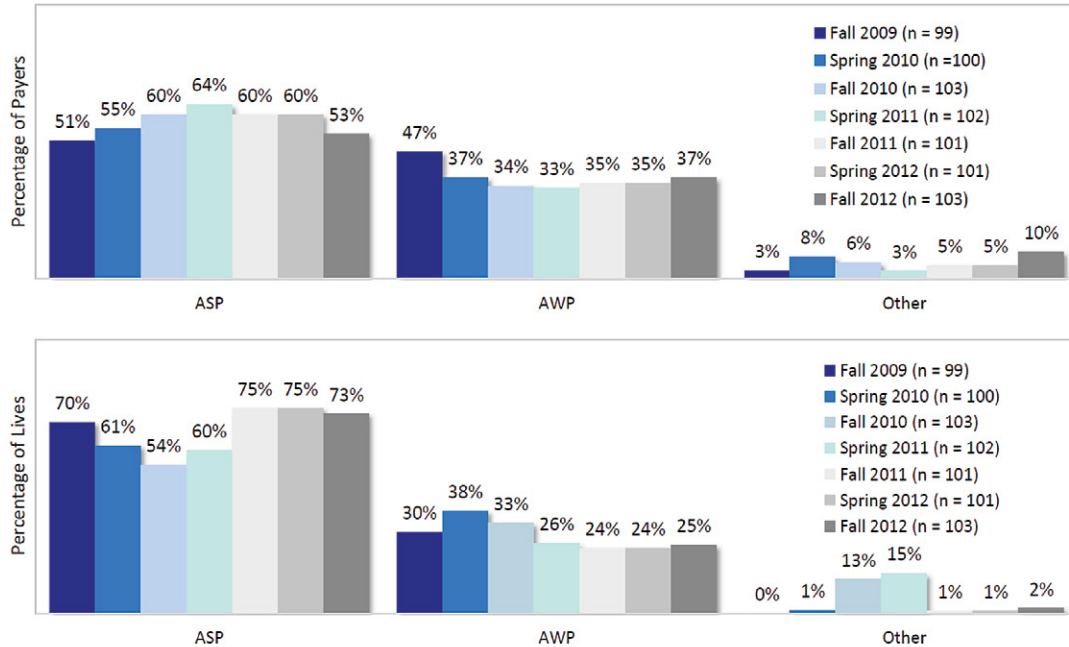
late 1990s may have been partly due to financial losses resulting from prescription drug capitation accepted by the physician practices.¹⁵¹ Medical group capitation with some financial risk for the cost of prescriptions administered in the medical office continues, but is not common.¹⁵² A concept proposed by Prometheus Payment—that of physician-based, severity-adjusted, evidence-based case rates—is being tested, but case rates initially will not include prescription drugs.¹⁵³ In 2011, office-administered drugs for 64% of payers and 60% of covered lives were paid on the basis of the ASP benchmark. (see Exhibit III-22).¹⁵⁰

For cost control reasons, some private payers require direct supply of physician office drugs by a specialty distributor under contract with the payer. In this scenario, the physician does

not buy and bill for the drug, but rather the drug is shipped to the physician office by the supplier, which then bills the payer at a contracted price. The physician bills the payer only for the professional services required to administer the drug. Prevalence of “white bagging” (specialty pharmacy ships drug directly to provider for patient administration) and “brown bagging” (specialty pharmacy ships drug to the patient, for delivery to the provider for patient administration) is shown in Exhibit III-23.

Home Health. Private purchasers pay for home health professional services on a per diem, per-visit or per episode basis. In the commercial sector, prescription drugs administered in the home setting are paid separately to home-infusion pharmacies on a FFS basis.¹⁵⁴

EXHIBIT III-22. PREDOMINANT REIMBURSEMENT METHODOLOGY IN THE PHYSICIAN-OFFICE SETTING



Zitter Health Insights • Managed Markets Research • © 2013 All rights reserved The Managed Care Biologics and Injectables Index, Fall 2012

Source: *Managed Care Biologics and Injectables Index, Zitter Health Insights, Fall 2012.*¹⁵⁰ Used with permission.

EXHIBIT III-23. SPECIALTY PHARMACY DISTRIBUTION TO PHYSICIAN OFFICE

DRUG VOLUME DISTRIBUTED IN PHYSICIAN OFFICE

PRIMARY BILLING PROCESSES	WEIGHTED AVERAGE VOLUME 2011		WEIGHTED AVERAGE VOLUME 2012	
	INFUSED CHEMO DRUGS	INFUSED NONCHEMO DRUGS	INFUSED CHEMO DRUGS	INFUSED NONCHEMO DRUGS
Physician buy and bill (provider uses stock and bills plan)	64%	38%	60%	36%
Specialty pharmacy provider (SPP) (a pharmacy or distributor ships to provider's office and provider does not bill for the drug)	25%	44%	32%	51%
Other	6%	7%	6%	10%
Brown bag (member takes drug to the provider's office for administration)	5%	11%	1%	1%

Source: *Medical Pharmacy & Oncology Trend Report. Third Edition, 2012. Available at <http://www.icorehealthcare.com/icore-resources/trend-report.aspx>. Used with permission.*

IV. How Products, Services, and Payments Flow Through Channels of Distribution

The complexity of drug payment can be made more comprehensible by diagrams that show the multitude of entities that are involved in various distribution channels.

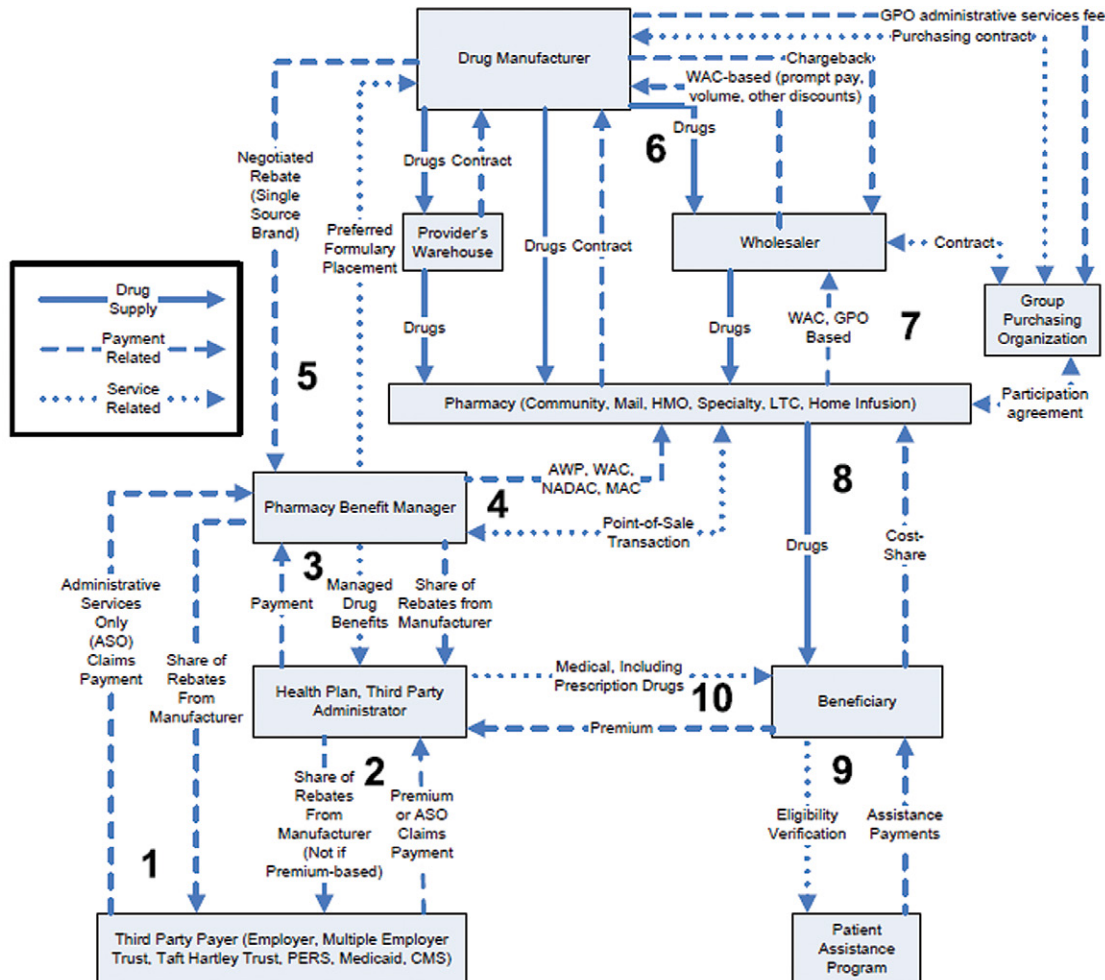
The two principal models of drug payment and pharmacy benefit financing in the U.S. health care system in 2013 are:

- Pharmacy benefit other than Medicare prescription drug benefit (see Exhibit IV-1); and

- Medicare prescription drug benefit (see Exhibit IV-2).
- Key stakeholder relationships are highlighted in these schematics. Only the first instance of each stakeholder relationship is shown. The relationships are described below.

1. **Payer carve-out to PBM.** A self-insured and self-administered private-sector or government purchaser may carve out pharmacy benefits from the overall health plan and contract directly with a PBM for their provision. With the exception of Medicare Part D (see Exhibit IV-2), PBMs generally do not take financial risk for prescription drug cost and utilization. Drugs supplied through pharmacies based on a PBM contract are paid on a negotiated basis, and the contract formula usually centers on AWP, WAC, MAC or

EXHIBIT IV-1. PHARMACY BENEFIT (OTHER THAN MEDICARE PRESCRIPTION DRUG BENEFIT)



customers share rebates with them as negotiated in the ASC agreement.

State Medicaid programs may contract with health plans (MCOs) for their beneficiaries (managed Medicaid), including provision of prescription drugs. The drug portion of the premium may reflect average AAC pricing, as implemented in each state. Drug sales for state Medicaid beneficiaries enrolled in health plans are subject to statutory rebates.

A self-insured employer may participate in a group purchasing organization (GPO) that can build preferred relationships with vendors, including PBMs, mail-order, and specialty pharmacies, based on price concessions, services, and service guarantees. The Human Resource Policy Association's Transparency in Drug Purchasing Solutions (TIPPS) initiative is an example of such an organization.^{133,155}

3. Health plan to PBM arrangements. A health plan or third-party administrator (TPA) may contract with a PBM to provide pharmacy benefits to beneficiaries. The drug payment basis is typically a percentage of AWP or WAC for the ingredient cost, plus a dispensing fee and perhaps other fees, such as a claims administrative fee and service fees, such as for performance of disease management and adherence programs. Agreements may require disclosure of manufacturer rebates received by the PBM as well as sharing of a portion of the rebate; or may instead stipulate a fixed rebate payment per retail and mail order prescription.

4. Relationship between PBM and network pharmacies. PBM provider networks may include several types of pharmacies and pharmacist services, including community, mail-order, health plan (staff and group models), specialty, LTC, compounding, and home-infusion. PBMs may contract directly with pharmacies or through Pharmacy Services Administrative Organizations (PSAOs), or they may own these entities outright. According to one study, "PSAOs improve contracting efficiency for independent pharmacies, and allow them to contract with PBMs at discount rates that are comparable to those received by larger retail chains."¹⁵⁶ Pharmacies are paid on a formula basis, typically the lower of a contract price or the U & C price. The contract price is the sum of the discounted AWP or WAC plus a dispensing fee, and MAC typically is used for pricing the ingredient cost for multiple-source drugs. The actual payment to the pharmacy is the lower of the contract price or U & C price minus the member cost-share amount.

5. Manufacturer to PBM relationships. PBMs, health plans that offer pharmacy benefits, PDPs, and MA-PDs develop drug formularies and negotiate manufacturer drug price concessions relative to coverage policy, formulary placement of specific drugs, beneficiary cost-share, and utilization management procedures. Manufacturer rebates also typically reflect the plan's ability to achieve volume, market share, and other contracted performance targets.

6. Manufacturer to wholesaler relationships. Manufacturers may sell drugs to pharmacies through drug wholesalers or to warehouses owned by drug chains. Large pharmacy chains may self-warehouse, but may be unable to negotiate manufacturer discounts below WAC for single-source branded drugs. The retail community pharmacy class of trade is typically not offered market share rebates on single-source branded drugs. In testimony before a Congressional committee in 2004, a Wal-Mart executive stated: "For branded drug products, Wal-Mart has little or no ability to negotiate discounts below the published WAC. Wal-Mart has no greater leverage for branded drug products than any other retail class of trade pharmacy provider."¹⁵⁷

7. Pharmacy purchase of drug inventory. Community, specialty, and other types of pharmacies may purchase drugs directly from wholesalers, or may join GPOs to generate increased negotiating leverage by combining purchase volume. GPOs may offer members owned or affiliated wholesaler-distributor service arrangements. GPO fees typically are up to 3% of product purchase dollars.¹⁵⁸

8. Patient purchase of prescription drugs. Beneficiaries pay a per-prescription cost share as stipulated in the benefit design, depending on site of dispensing, coverage, brand or generic category and formulary tier of the dispensed drug. The beneficiary may be responsible for meeting an annual out-of-pocket deductible that may apply to all health benefits costs and/or may be specific to the pharmacy benefit. A maximum benefit may apply.³⁸ Patients without prescription drug coverage pay the pharmacy usual and customary price, or take advantage of special pharmacy club prices on multiple source generics.

9. Patient assistance programs assist patients in meeting cost-share obligation. Patient assistance programs (PAPs), sponsored by manufacturers and administered by service providers, PBMs, and charitable organizations, are available to help eligible individuals meet the out-of-pocket cost of medications when patients are without pharmacy benefit coverage and/or when patients meet specific, sponsor-defined financial criteria. The Partnership for Prescription Assistance (PPARx, www.pparx.org) is an example of a referral service to assistance resources.

10. Patient relationship to their health plan. Workers electing health benefits through a group may be required to pay a portion of the premium cost in addition to any deductibles, copayments, and coinsurance that the benefit design may stipulate. The employee's share of the monthly health insurance premium is deducted from salary by the employer. People purchasing health insurance directly from health insurers, and as of January 2014, who purchase health insurance through state-based Health Insurance Exchanges, pay (and/or their third party sponsors pay) premiums directly to the health insurers.

11. CMS contracts with Part D and MA-PD providers. CMS pays the Part D provider in three ways. The first is a direct risk-adjusted (according to health and demographic characteristics) premium subsidy, the second is a low-income

subsidy, and the last is a reinsurance subsidy. An annual reconciliation may result in additional payments to the provider or in payment recouped by the government. Employers and unions that sponsor retiree benefits that offer no less than the Medicare drug benefit qualify for a Retiree Drug Subsidy equal to 28% of eligible retiree drug costs.^{88, 91} Beginning Jan. 1, 2013, the PPACA eliminated the sponsor's tax deduction to the extent of the subsidy received.¹⁵⁹

12. Medicare beneficiary relationships to PDP and MA-PD providers. Most Part D beneficiaries must pay a monthly premium to the Part D sponsor. The MMA requires that beneficiary premiums must reflect 25.5% of the national average standardized bid across all Part D plans.¹⁶⁰ Low-income and Medi/Medi beneficiaries pay a lower or no premium, cost-share and deductible.

V. Issues and Implications For Stakeholders

■ ■ No clear successor to the AWP benchmark

Issue

Subsequent to the March 17, 2009, Memorandum and Order referred to earlier (see Section II, Payment Benchmarks), it appeared that AWP would no longer be widely published by the end of 2011. However, as of the *Guide's* publication date, AWP remains a dominant pricing benchmark in commercial markets. In public markets, PPACA changed the Medicaid benchmark definition from estimated acquisition cost to actual acquisition cost, and finalized the use of a weighted average AMP in FUL calculation.

WAC has been suggested as a possible replacement for AWP, because it more closely approximates actual transaction price for single-source-branded products, because it currently exists in most published pricing references, and because it will continue to be published for the foreseeable future. However, WAC has not been a viable option heretofore because many drugs, particularly multiple-source drugs, do not have published WAC prices, and because WAC does not approximate actual transaction price for many single source branded drugs in competitive therapeutic classes and for the vast majority of multiple-source drugs.¹⁶¹ However, when combined with other benchmarks that are used primarily for generics (MAC, FUL), a WAC/MAC/FUL based solution has high coverage of NDCs.

Implications

- Pharmaceutical manufacturers may reconsider rebates currently offered for preferred formulary placement and attainment of market share targets, because it may be necessary to calculate AMP net of such payment. Pharmaceutical manufacturers and other stakeholders in the channels of distribution may reconsider fees paid in light of whether they qualify as exempt bona fide service fees.
- Third-party payers may benefit from replacement of AWP with an actual transaction price benchmark because the new benchmark would provide transparency both with respect to acquisition cost and markup. In addition, such a benchmark may enable payers to more effectively leverage their market power in negotiating price concessions with pharmaceutical manufacturers. That said, the closer to actual acquisition price that is paid the drug ingredient, the more closely the dispensing fee must reflect actual dispensing cost.
- Payment to retail community, mail-order, and specialty pharmacies on the basis of an actual transaction price benchmark may result in reduction in the gross margins of these pharmacies, the extent of which would depend on the level of markup and additional fees paid. Without upward adjustment of product markups or increases in dispensing fees for pharmacy services, there may be adverse effects, for example on reduced pharmacy participation in provider networks, and on reduced availability of multiple source generics.
- Replacing AWP with ASP has been shown to be an effective method to significantly reduce drug payments for Medicare. ASP, however, does not lower the cost of drugs between the manufacturer and distributor or the manufacturer and provider; there is some evidence that ASP may raise drug cost by giving providers incentive to prescribe more expensive drugs, because doing so drives higher absolute dollar margins. With ASP, it is the end provider of services, not the manufacturer, whose gross margin is most affected.
- Use of a simple ASP plus some percentage, absent any additional controls, creates the financial incentive for prescribers to select a higher-cost, higher-dollar product versus a lower-cost, lower-dollar product. For example, 6% of a drug with a \$500 ASP for a provider–purchaser has a \$30 margin, while a therapeutic alternative with a \$100 ASP has only a \$6 margin. It has been recommended that multiple source generic injectable reimbursement be increased to ASP+50%, leaving single source brand injectables at ASP+6%, because the former would allow the provider an improved margin, and the multiple source generic with that markup may still be less costly for the payer relative to a therapeutically similar single source brand product.
- As noted in a statement on AWP reform from the Biotechnology Industry Association (BIO), “If changes to AWP are made, these changes should take into account the professional services of physicians and other providers that accompany the administration of covered products,” and offers the following in explanation: “Some provider organizations have presented evidence that their members are not being adequately reimbursed for their professional services and that any differential between AWP and provider acquisition cost goes to make up this gap.”¹⁶² In this and in similar cases, movement from AWP to an actual transaction price benchmark will necessitate valuation and fair separate compensation for services related to provider drug handling and administration. Similarly, use of an actual transaction price for drug ingredient cost in community and mail-order pharmacies has precipitated upward adjustment of dispensing fees in several State Medicaid programs.

- Medicare's ASP reimbursement formula has made it difficult for some providers to recover their full acquisition cost, mainly those who purchase physician-administered drugs in small quantities and who therefore do not qualify for or are unable to earn particular discounts or rebates. This reimbursement formula also has forced physicians to be more vigilant about collecting full patient cost sharing. As a result, manufacturers report increasing demand for coinsurance assistance from Patient Assistance Programs (PAPs).^{49,163} In addition, patient service levels may be affected negatively where physicians refer patients to others for drug administration, rather than acquire medication for in-office administration, due to insufficient reimbursement.
- A cause and effect relationship has been suggested between ASP-based reimbursement and shortage of many injectable multiple source generic drugs. A recent staff report of the Committee on Oversight & Government Reform of the US House of Representatives concludes: "The MMA (Medicare Modernization Act) decreased reimbursements that Medicare pays for administering injectable medications to levels that are often below the cost that it takes for manufacturers to produce the drugs. Manufacturers are reluctant to raise prices for these drugs above what Medicare reimburses providers who administer them. According to information obtained by the Committee, manufacturers are currently producing many oncology drugs at a loss. Regardless of industry, when a supplier is losing money on a particular product they have an incentive to shift production to a product that earns a profit. Therefore, common sense suggests that the MMA would lead to fewer suppliers producing oncology drugs and the evidence indicates this is exactly what has happened."¹⁶⁴
- An actual transaction price benchmark could disadvantage community pharmacies in several ways. First, it may not reflect pharmacy acquisition cost, such as when including wholesaler prompt-pay discounts that may not be passed on to the purchaser. Smaller community pharmacies may be less able to obtain the net price concessions available to larger purchasers or other types of purchasers that are more capable of moving product market share. Also, if the actual transaction price benchmark is calculated on data that is several months old, and if this benchmark becomes the basis for current payment purposes (as is true for ASP), then this may misrepresent a current transaction price to the disadvantage of the purchaser. Finally, pharmacies would find financially unsustainable if the dispensing fee is not adjusted to reflect actual pharmacy dispensing costs concurrently with implementation of actual acquisition cost based reimbursement.

- MCOs that adopt payment methods benchmarked to an actual transaction price should carefully consider the immediate and long-term effects on providers and patients. Careful consideration of how overall provider services and relationships will change as a result of any drug payment policy changes should include the impact on access to care and the ability of providers to supply quality services. For example, if ASP is determined to be a better benchmark than AWP, what change in payment method is appropriate to ensure that providers are recovering at least their AAC? Total drug payment to service providers has two principal components: the drug product and the professional services associated with dispensing or administering the product. Because providers rely on total compensation to meet their costs for the product and professional services, reduction in the reimbursement amount for one component will likely create pressure to increase the amount of reimbursement for the second component. How should total compensation ensure that providers maintain a reasonable profit?

■ ■ Bundling (combining) drugs with services

Issue

Combining drug reimbursement with related clinical services transfers the drug's economic responsibility and risk from the payer to the provider.¹⁶⁵ Medicare has used this technique for managing hospital inpatient (diagnosis-related group [DRG]) and outpatient (APC) drug spending, other acute care services (e.g., skilled nursing facilities [SNFs]), hospice and dialysis services (composite rate). Accountable Care Organization (ACO) pilots represent another approach to bundling, although outpatient prescription drugs are not currently included in CMS-sponsored ACO pilots. As required by PPACA, CMS is exploring additional service and payment bundling approaches. In the private sector, some medical groups have received per member per month (PMPM) capitation payments inclusive of shared financial risk for prescription drugs, and most private health plans pay for inpatient services using a per diem or DRG rate that includes drugs. Bundling has been proposed in other settings (such as primary care in a medical home setting), across settings (such as hospital and post-discharge care) and with particular disease severity refinements to more accurately reflect provider cost and ability to manage risk.

Implications

- The manner of bundling—what is included and excluded in the bundle—will drive stakeholder incentives. If prescription drugs administered incident to an office or clinic visit and pharmacy benefit are included in the delegated service and bundled payment, then it is likely that, within limits, drug formulary, drug coverage policy and enforcement are also delegated, so that the at-risk provider has both the responsibility and tools it needs to manage this risk. A downside risk of bundling is inappropriate reduction in services provided or substitution of lesser cost therapies, either of which may reduce quality of care.
- If prescription drugs administered incident to an office or clinic visit are included in the bundled payment, but the pharmacy benefit is excluded, as is the case in CMS pilot ACOs, then the organization may lack responsibility to maximize overall healthcare value for its assigned patient population. For example, because outpatient prescription drug costs remain separate in such arrangements, prescribers may favor self-administered drugs (not a system responsibility) over office-administered drugs (a system responsibility), when clinically appropriate.

■ ■ Pricing transparency: Is it meaningful?

Issue

In the private sector, increasing pressure has been placed on PBMs by many stakeholders including drug plan sponsors, government agencies and consumer organizations, to disclose pricing concessions and rebates. Furthermore, increasing penetration of high-deductible Consumer Driven Health Care plans will lead to increased beneficiary price sensitivity and demand for greater pharmaceuticals price transparency. Many PBMs have increased pricing transparency to their clients, reportedly including increased pass-through of manufacturer rebates. However PBM's prescription drug pricing transparency does not necessarily extend to the beneficiary.

Implications

- At the same time that some payers, most notably Medicare, are packaging services with drugs, the drive to greater pricing transparency may make it difficult for intermediaries and pharmacies to fund the provision of some drug administration-related services within the lower net drug price that is paid.

- Pricing transparency requires PBMs to offer, price, and cost-justify drug-related services previously made available at no extra charge when they were funded through the margin between the amount paid to the pharmacy provider and the amount charged to the drug plan sponsor. New billable services likely will evolve to replace the lost revenue, possibly with process and outcome guarantees.
- Some PBM transparent pricing offers amount to a pass-through cost to the drug plan sponsor of the PBMs' individually negotiated network pharmacy payments. The PBM may be unwilling or unable to disclose underlying pricing with contracted pharmacies, but may offer an overall AWP-based pricing guarantee. However, the payer may perceive this as less transparent than a contractually specified AWP-discounted pricing formula.
- The CBO has observed that “the markets for some health care services are highly concentrated, and increasing transparency in such markets could lead to higher, rather than lower, prices.” In particular, “In health care, reduced competition might result if more transparent pricing revealed the prices negotiated between insurers and providers, especially in concentrated markets.”¹⁶⁶

■ ■ How significant will be biosimilars' market impact?

Issue

In the Biologics Price Competition and Innovation Act, a section of the PPACA, a licensure pathway was created for biological products that are demonstrated to be biosimilar to or interchangeable with an FDA-licensed biological product. A biological product is biosimilar if data show that the product is highly similar to an already-approved biological product, notwithstanding minor differences in clinically inactive components; and that there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.¹⁶⁷

The biological product is “interchangeable if (1) it can be expected to produce the same clinical result as the reference product in any given patient and (2) the risk, in terms of safety or diminished efficacy of switching between the two products, is not greater than the use of the reference product without such alternation.”¹⁶⁸ The FDA has not yet implemented an approval process for biosimilars. Issues include: Will biosimilars have the same generic name as the originator brand? Will they be clinically interchangeable? Will FDA enable and will state law permit pharmacists to interchange a biosimilar for the innovator product,

under what circumstances and requiring what process?¹⁶⁹ Savings from use of biosimilars will be far less than has been experienced with small molecule multiple source generics. Assuming up to three generic manufacturers in the market due to technical, economic and regulatory challenges, biosimilars savings have been estimated at 10–25% relative to the innovator brand.¹⁷⁰ The Medicare Part B payment amount for a biosimilar product must be based on the sum of its own average sales price (ASP), plus 6% of the higher reference product ASP.

Implications

- Will biosimilars have the same generic name as the originator brand? If yes, will state pharmacy law allow and will pharmacists be willing to treat them interchangeably as A rated generics are commonly treated today?¹⁷¹
- Which biosimilars will be interchangeable with the originator brand, in which states, under what circumstances and requiring what process? The FDA states that an interchangeable product may be substituted for the reference product without the authorization of the health care provider. However, if the FDA infrequently grants interchangeable status to biosimilars, then easy substitution will be limited. In light of quality of care and liability considerations, payer and PBM pharmacy and therapeutics committees will be cautious in establishing coverage policies for biosimilars, and prescribers will be cautious in prescribing them.
- Will the Medicare biosimilar reimbursement formula result in manufacturers of originator drugs lowering their prices to minimize loss of sales attributable to a higher margin when the biosimilar is used?
- How will availability of biosimilars impact therapy cost and year-over-year trend? If few biosimilars carry an FDA interchangeable designation, and if initial payer, prescriber and pharmacist response is cautious, then initial biosimilar impact on overall prescription drug cost will be marginal.

■ ■ PBM Dilemma: Challenges in the face of generic prescription clubs and copay coupons

Issue

If not covered by PBMs, generics available through retail community pharmacy generic prescription clubs disintermediate PBMs, by reducing the volume of tier 1 generics adjudicated and paid through PBMs. Copay coupons and copay cards disintermediate PBMs with respect to high priced branded drugs, by increasing the frequency and cost of non-preferred tier 3 and 4 branded drug adjudicated and paid through the PBMs,

and reducing PBM rebates collected. Together these impacts at the bottom and top of the drug formulary potentially raise PBM average drug cost, reduce PBM effectiveness for the payer, limit PBM profitability, reduce PBM relevancy and reduce PBM market power.

Implications

- Increasing market penetration of generic prescription clubs reduce generic prescription costs for the beneficiary, eliminate these costs for the third party payer, make therapy adherence difficult for payer's PBM to track or intervene with, and return market power and patient relationship control to the retail community pharmacy.
- Increasing availability and utilization of copay coupons increases payers' drug cost while, in the short term, reducing patient drug costs. They challenge payer drug coverage policies that seek to limit use of non-preferred drugs, and reduce PBM ability to manage access to and utilization of these expensive drugs, returning market power and patient relationship control to the pharmaceutical manufacturer.

■ ■ High deductible plan cost shift to the beneficiary

Issue

The current trend in benefit design toward consumer-directed health care (CDHC) increases beneficiary exposure to additional costs in the form of deductibles and beneficiary cost-share at the point of service (i.e., copayments and coinsurance). From the health plan and employer perspective, CDHC transfers cost to the beneficiary, reducing benefit spend, and increases beneficiary risk for and sensitivity to health care prices, possibly reducing trend (i.e., growth in benefit cost over time).

Implications

- Higher beneficiary cost results in increased cost sensitivity when using medical benefits and prescription drugs.¹⁷² But because beneficiaries lack medical training, expertise and information, and despite access to Internet-based information, they may not make wise cost/benefit tradeoffs.
- Pharmacists have demonstrated effectiveness in helping patients manage their out-of-pocket costs for prescription drugs and pharmacy services.¹⁷³ Pharmacy providers can help beneficiaries in CDHC plans reduce out-of-pocket cost by therapeutic selection of generic and certain higher-value single-source brand drugs. Increased beneficiary cost-sharing may increase the need and demand for these services.

- If beneficiary cost exposure and access are not equivalent across treatment settings, care delivery may migrate to settings that expose the beneficiary to the lowest cost-share. For example, in some commercial health benefit plans, drugs administered in the physician office, covered under the medical benefit, require no cost-share while drugs with a similar therapeutic objective covered under the pharmacy benefit may be considered specialty pharmaceuticals and require a coinsurance payment.

■ ■ Role of comparative-effectiveness research findings to structure drug benefits and manage drug access

Issue

A total of \$1.1 billion of the \$787 billion economic stimulus bill approved by Congress in February 2009 (Public Law 111-5, the American Recovery and Reinvestment Act of 2009 [ARRA]) provided significant one-time funding through September 30, 2010 for comparative-effectiveness research to evaluate drugs, medical devices, surgery, and other treatments. Although the focus of the funding of this research was to be clinical effectiveness, incorporating evaluation of cost-effectiveness was not precluded. Since 2005 and with a much smaller budget, the Agency for Healthcare Research and Quality has sponsored comparative-effectiveness research.^{174, 175} Many state Medicaid programs, private payers, and provider groups sponsor similar efforts.¹⁷⁶

PPACA mandated establishment of the Patient-Centered Outcomes Research Institute (PCORI) to examine the “relative health outcomes, clinical effectiveness, and appropriateness” of different medical treatments by evaluating existing studies and conducting its own studies. PCORI will not have the power to mandate or endorse coverage rules or reimbursement for any particular treatment. Medicare may consider PCORI’s findings when deciding what procedures it will cover, but the agency must also consider public input. PPACA forbids PCORI from using “a dollars per quality adjusted life year” or similar measure that discounts the value of a life because of an individual’s disability, as a threshold for procedure effectiveness.¹⁷⁷ PPACA also established the Independent Payment Advisory Board (IPAB) with authority to issue recommendations to reduce the growth in Medicare spending, and provide recommendations to Congress. IPAB is directed to recommend savings for Medicare if the per capita growth in Medicare spending exceeds defined target growth rates.¹⁷⁸

Implications

- Concern exists that despite the report language that accompanied ARRA and PCORI, comparative-effectiveness research may be used by insurers or by the government primarily to deny coverage for more expensive treatments or to ration care.
- Comparative effectiveness methods and standards can be controversial. For example, controversy exists about the validity of inferring causation about treatments and other health interventions based on observational data. Another issue is whether comparative effectiveness should address cost: For example, is an incremental benefit always “worth it”? Who will decide and on what basis and with what input will that decision be made?¹⁷⁹
- It may prove difficult to apply comparative effectiveness methods and standards to FDA-approved orphan drugs which by law target populations of fewer than 200,000 lives in the US, and to ‘ultra-orphan’ drugs which may target just a few hundred or a few thousand patients, for whom there are no therapeutic alternatives.
- That the results of comparative-effectiveness research may be applied in ways which incorporate payment is substantiated in a June 2009 MedPAC Report to the Congress:¹⁰¹

“To help improve the value of Medicare spending, we discuss three pricing strategies that use information about a drug’s clinical effectiveness when paying for it under Part B and Part D:

 - *Reference pricing: Set a drug’s payment rate no higher than the cost of currently available treatments unless evidence shows that the drug improves beneficiaries’ outcomes.*
 - *Payment for results: Link a drug’s payment to beneficiaries’ outcomes through risk-sharing agreements with manufacturers.*
 - *Bundling: Create payment bundles for groups of clinically associated products and services.”*
- Others argue that cost-effectiveness information will instead lead to improved quality, better outcomes, more efficient, and less variable delivery of care.
- An important challenge in application of comparative-effectiveness research will be the balance of societal and population needs versus unique patient circumstances at the point of care. To some, this suggests the need to consider the meaning of rationing.¹⁸⁰

- Challenges include dissemination of cost-effectiveness rationale and information to patients, advocacy groups and providers, implementation of decision support tools at the point of care delivery, and wide-spread and consistent application of electronic medical records technology.

■ ■ Will pharmaceutical manufacturers accept risk for desired therapeutic outcomes from use of their products?

Issue

Pharmaceutical manufacturers are experimenting with accepting risk for the therapeutic outcome of their drugs in exchange for insurance coverage that would otherwise be denied or restricted. Published reports describe arrangements between private insurers and manufacturers of diabetes and osteoporosis drugs that place the manufacturer at risk for treatment costs attributed to failure of the drug to achieve the stated therapeutic goals.¹⁸¹ One example is a relationship between a U.S. oncology drug manufacturer and the United Kingdom's National Health System.^{182, 183}

Implications

- These arrangements reflect increasing cost sensitivity of the marketplace and the need for cost to be justified by value to obtain access for a more expensive drug in a crowded therapeutic category. Despite implementation issues, risk-sharing arrangements could become more common in response to even greater cost pressure.
 - Should risk for desired therapeutic outcomes be considered a warranty, a type of insurance, providers' assumed risk in prescribing and managing a particular therapeutic course, or a combination of these?^{184, 185} For example, which of these might be the best description of the Medicare "never events" policy?¹⁸⁶
 - Acceptance of financial risk for therapeutic outcomes presents extraordinary challenges to pharmaceutical manufacturers. The success of these programs will depend on resolution of several issues such as those shown below:
 - Significant variation in patient response should be expected over time, particularly for patients with multiple medical problems, subject to multiple therapeutic interventions, including the targeted drug therapy for which the manufacturer is at risk. In observational data, it may prove difficult to link specific drug treatment causally to a particular outcome for a particular chronically ill patient population, much less for a particular patient.
- Assuming economic risk for a health outcome is the equivalent of insuring patient care, albeit for a targeted purpose. Pharmaceutical manufacturers do not have experience as insurers, nor is the manufacturer business model set up for this purpose. Investors in pharmaceutical stocks anticipate risk in research and development, but do not anticipate risk related to outcome of therapy.
 - A manufacturer could hire or contract to obtain necessary risk assessment and management expertise. Doing so will entail a certain cost. An additional cost is incurred in underwriting outcome risk, which manufacturers might retain internally or seek through a third-party insurance policy. These costs could be financed through increasing product price or result in lower manufacturer profitability.
 - It is not clear how state insurance regulators will respond to manufacturer-sponsored outcome risk arrangements. Will this be considered insurance subject to capital requirements and regulation? Smaller manufacturers may be financially unable to underwrite outcome risk programs, even if their products are ideal candidates, leaving them at a competitive disadvantage to larger manufacturers of competing products (or result in limited availability of the small manufacturer's product).
 - These arrangements may become less about financial risk and more about market entry and market positioning, in that nimble manufacturers may be able to use effectiveness guarantees to create payer preference and market barriers to equally or more efficacious products. Such guarantees also could be used on a direct-to-consumer basis by manufacturers, in an effort to circumvent a product's formulary status.
 - These considerations suggest that health outcome risk assumption by pharmaceutical manufacturers will require careful study before becoming a routine part of the payer-manufacturer relationship.

■ ■ Orphan and ultra-orphan drugs

Issue

High pricing for orphan and ultra-orphan drugs, coupled with an increasing number of orphan drugs in development, suggests a long-term affordability concern both for patients treated for rare disease and the health benefit programs that pay for that treatment. Payers today often limit access to orphan and ultra-orphan drugs to FDA-approved indications, with little coverage for off-label use—but may be unable to deny access altogether in view of Essential Health Benefits mandates under PPACA. PPACA

provides for premium stabilization, in the form of risk adjustment, reinsurance and risk corridors, to protect against adverse risk selection into health plans. However because CMS will not initially use prescription drugs as a predictor of risk, PPACA premium stabilization will not address imbalance in patient administration of orphan drugs.¹⁸⁷

Implications

- Until now, payers have not felt compelled to address orphan drug costs because the overall budget impact to any one payer has been small. When even higher prices and greater numbers of orphan drugs **change** the overall cost impact, private and government payers are likely to consider new cost controls that open discussion about “What is a life worth?”
- In order to address patient and payer affordability, it may be worthwhile for the marketplace to evaluate the feasibility of reinsurance for the aggregate cost of orphan and ultra-orphan drugs.

■ ■ How will greater use of pharmacogenomics affect drug pricing?

Issue

A goal of pharmacogenomics is to “provide clinicians with tools to assess risks and benefits associated using available medicines for particular patients to select therapies and treatments tailored to each patient. In so doing, pharmacogenomics should enable direct management of individual patient-drug response for many conditions.” One example is HER2/neu testing of metastatic breast cancer patients to determine potential responsiveness to Herceptin.¹⁸⁸ Another is the use of KRAS testing to determine whether Erbitux or Vectibix would be beneficial in the treatment of colorectal cancer in particular patients.¹⁸⁹

Implications

- Although costs will be associated with the performance of pharmacogenomic tests, drug ingredient and associated drug administration and office visit costs would be saved by avoiding administration of drugs where tests show particular patients would be poor responders, and for other patients for whom particular drugs would be unsafe.
- Consistent application of pharmacogenomic tests in appropriate cases would make it more likely that patients identified as good candidates for particular drug therapy would be offered that therapy, if otherwise clinically indicated.
- Health information technology and systems infrastructure can support informed use of pharmacogenomic tests and use of prescription drugs dependent on the outcome of those tests at the point of care.¹⁹⁰
- It will be important for payers to develop coverage policies and tracking systems to link availability and results of particular pharmacogenomic tests to the utilization of particular pharmaceuticals for patients meeting specified clinical conditions.
- Will drugs linked to pharmacogenomic tests justify higher prices because there is less “waste” of drug in patients for whom the tests predict poor results, and better outcomes for the fewer patients to whom these drugs are administered?

VI. Acronym List

Pharmaceutical payment is complex, made more so by factors such as the historical combination of reimbursement of pharmacy professional services with payment for pharmaceutical products, the number of entities involved in the distribution of pharmaceuticals, and the more than 10,000 unique drugs with vastly different prices distributed among the drug categories of brand, generic, and multi-source. In addition, a complex relationship exists between the use of pharmaceuticals and of other medical resources in particular therapies, related to a host of factors, including site of care delivery, the type of prescriber, method and amount of payment, benefit design, payer coverage policies, results of practice guidelines and comparative-effectiveness reviews, patient medical condition, patient cost-share responsibility, and patient preference.

Today, biologics and injectable drugs that were at one time covered primarily in the medical benefit often have been transferred to the pharmacy benefit, and these two health benefit categories have used much different payment methods. Pharmaceuticals and biotechnology therapeutics, and their associated costs, are increasingly visible and of concern to public and private third-party payers. As a result of direct-to-consumer advertising and increased cost-sharing, they have become increasingly visible and of concern to patients as well. What may be less evident to both, representing a major challenge for future development, are these products' value for money.

It is also clear that, after more than 40 years of using AWP as the primary benchmark for determining pharmaceutical payment, this benchmark has been manipulated and does not approximate the actual acquisition cost to the end dispenser of the drug. The search continues for a replacement for AWP for pharmaceutical payment that will encourage delivery of high-quality products and stimulate efficient delivery of pharmacy products and services without reducing access for patients. Understanding pharmaceutical payment and the factors that affect payment is an important step in achieving the aforementioned goals.

AMCP hopes that the information in this *Guide* will ultimately prove to be “quality data that informs the debate” and thus leads to better decisions. The Academy welcomes your feedback about this *Guide*, which can be submitted at: <http://www.amcp.org/contactus/>

AAC	actual acquisition cost
ACA	Patient Protection and Affordable Care Act (also referred to as PPACA)
ACO	Accountable Care Organization
AIDS	acquired immunodeficiency syndrome
AMCP	Academy of Managed Care Pharmacy
AMP	average manufacturer price
APC	ambulatory payment classification
GCN	generic code number (6-character, First Databank)
GPI	generic product identifier (14-character, Medi-Span)
GPO	group purchasing organization
ASC	Administrative Services Contract
ASC	ambulatory surgical center
ASO	Administrative Services Only
ASP	average sales price
AWP	average wholesale price
BP	best price
CAP (or RxCAP)	Competitive Acquisition Program (for drugs and biologicals)
CARE	Comprehensive AIDS Resource Emergency
CBO	Congressional Budget Office
CDHC	consumer-directed health care
CMP	competitive medical plan
CMS	Centers for Medicare & Medicaid Services
COT	class of trade
CPI-U	Consumer Price Index—Urban
CPT	current procedural terminology
CRS	Congressional Research Service
DHHS	Department of Health and Human Services (also referred to as HHS)
DME	durable medical equipment
DoD	Department of Defense
DOJ	Department of Justice
DP	direct price
DRA	Deficit Reduction Act of 2005

VI. ACRONYM LIST

DRG	diagnosis-related group	MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
DSH	disproportionate-share hospital	NADAC	National Average Drug Acquisition Cost
EAC	estimated acquisition cost	NARP	National Average Retail Price
EHB	Health Benefit	NDC	national drug code (11-character)
EPO	exclusive provider organization	non-FAMP	nonfederal average manufacturer price
ERISA	Employee Retirement and Income Security Act of 1974	OBRA 90	Omnibus Budget Reconciliation Act of 1990
ESRD	end-stage renal disease	OIG	Office of Inspector General (of the Department of Health and Human Services)
FCP	federal ceiling price	OPA	Office of Pharmacy Affairs
FDA	Food and Drug Administration	OPD	outpatient prescription drug
FDB	First Databank, Inc.	OPPS	outpatient prospective payment system
FFS	fee for service	OTC	over-the-counter
FMAP	Federal Medical Assistance Percentage	P4P	pay for performance
FPL	Federal Poverty Level	PA	prior authorization
FQHC	federally qualified health center	PAB	Pharmacy Affairs Branch
FSS	Federal Supply Schedule	PAP	patient assistance program
FUL	federal upper limit	PBM	pharmacy benefit manager
HCPCS	Healthcare Common Procedure Coding System	PDL	Preferred Drug List
HDHP/SO	high deductible health plan with savings option	PDP	prescription drug plan
HMO	health maintenance organization	PERS	Public Employees' Retirement System (e.g., California Public Employees' Retirement System [CalPERS])
HOPD	hospital outpatient department	PHS	Public Health Service
HRSA	Health Resources and Services Administration	PMPM	per member per month
IHS	Indian Health Service	PMPY	per member per year
IPA	independent practice association	POS	point of sale or point of service
IPAB	Independent Payment Advisory Board	PPAC	Patient Protection and Affordable Care Act (also referred to as ACA)
IVIG	intravenous immune globulin	PPARx	Partnership for Prescription Assistance
KFF/HRET	Kaiser Family Foundation/Health Research and Educational Trust	PPO	preferred provider organization
LCA	least costly alternative	PPS	prospective payment system
LDL	low-density lipoprotein	PSAO	Pharmacy Services Administrative Organization
LTC	long-term care	PSO	provider-sponsored organization
MA-PD	Medicare Advantage–Prescription Drug Plan	RP	reference price
MAC	maximum allowable cost	SCHIP	State Children's Health Insurance Program
MCO	managed care organization		
MedPAC	Medicare Payment Advisory Commission		

VI. ACRONYM LIST

SCOD	specified covered outpatient drug	U & C	usual and customary (price)
SNF	skilled nursing facility	UCR	usual, customary, and reasonable
SPAP	State Pharmaceutical Assistance Program	URA	unit rebate amount
TIPPS	Transparency in Drug Purchasing Solutions	VA	Department of Veterans Affairs (Veterans Administration)
TMAC	therapeutic maximum allowable cost	WAC	wholesale acquisition cost
TPA	third-party (claims) administrator	WAMP	widely available market price
TrOOP	true out-of-pocket (Medicare Part D)		

VII. Glossary

340B Ceiling Price See Public Health Service 340B Ceiling Price.

340B Covered Entity Facilities and programs listed in the 340B statute as eligible to purchase drugs through the 340B program

340B Covered Drug A covered outpatient drug that is an FDA-approved prescription drug, an over-the-counter drug that is written on a prescription, a biological product that can be dispensed only by a prescription (other than a vaccine) or FDA-approved insulin. PPACA made special provision for access to FDA-designated orphan drugs by certain 340B covered entities.

340B Drug Pricing Program Section 340B of the Public Health Service Act (1992) requires drug manufacturers participating in the Medicaid Drug Rebate program to limit charges for outpatient drugs sold to covered entities.

5i drugs For purpose of calculation of AMP, 5i drugs are those that are inhaled, infused, instilled, implanted or that are injectable.

actual acquisition cost (AAC) Final cost of the pharmaceutical to the pharmacy or other health care provider after all discounts, rebates, and other price concessions are taken into account.

accountable care organization (ACO) A group of physicians, hospitals and/or other providers that are held accountable for quality of care provided and for annual overall Medicare spending for their patients, and who share in savings generated.

administrative services only (ASO) An arrangement in which a plan hires a third-party to deliver administrative services to the plan, such as claims processing and billing, but the plan bears the financial risk for claims. This is common in self-funded (also known as self-insured) health care plans.

affordable care act Health reform legislation signed into law on March 23, 2010.

allowed charge Price for a product or service negotiated between the provider and the health plan or other payer or its intermediary. The difference between the allowed charge and the provider's usual and customary (U & C) price is the "contractual discount."

ambulatory payment classification (APC) Method used by the Centers for Medicare & Medicaid Services (CMS) to implement prospective payment for ambulatory procedures. The APC clusters many different ambulatory procedures into groups for

purposes of payment. Both APCs and diagnosis-related groups (DRGs) represent groups of patients that are clinically alike and have roughly the same resource consumption. The APC is used in a similar fashion to the way in which DRGs are used for payment for inpatients; however, APCs depend on the procedures performed, whereas DRGs depend on the diagnoses treated.

authorized generic Drug approved by the FDA that the brand manufacturer subsequently chooses to market (or have marketed under sale or license) by generic name. The brand-name drug and the authorized generic are chemically identical.

average manufacturer price (AMP) Average price paid to a pharmaceutical manufacturer by wholesalers for drugs distributed to retail pharmacies, net of prompt-pay ("cash") discounts. AMP was a benchmark created by Congress in 1990 in calculating rebates owed Medicaid by pharmaceutical manufacturers. The Federal Supply Schedule (FSS) and 340B prices, as well as prices associated with direct sales to health maintenance organizations (HMOs) and hospitals, are excluded from AMP under the Medicaid rebate program. The Affordable Care Act revised the definition of AMP by replacing the term "retail pharmacy class of trade" with "retail community pharmacy." AMP is now defined as: "average price paid to a manufacturer for the drug by wholesalers for drugs, distributed to retail community pharmacies and retail community pharmacies that purchase drugs direct from the manufacturer."

average sales price (ASP) Section 303(c) of the Medicare Modernization Act (MMA) revised the drug payment methodology by creating a new pricing system based on a drug's ASP. Effective January 2005, Medicare began paying for the vast majority of Part B covered drugs and biologicals using a drug payment methodology based on the ASP. In accordance with section 1847A of the Social Security Act (the Act), manufacturers submit the ASP data for their products to CMS on a quarterly basis. These data include the manufacturer's total sales (in dollars) and number of units of a drug to all purchasers in the United States in a calendar quarter (excluding certain sales exempted by statute), with limited exceptions. The sales price is net of discounts such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, charge-backs, and rebates (other than rebates under section 1927 of the Act). Excluded from ASP are sales that are excluded from Best Price. CMS updates ASP drug pricing files for Medicare Part B drugs on a quarterly basis. Medicare Part B drugs and biologicals not paid on a cost or prospective payment basis are paid based on the ASP methodology, and payment to providers is 106% of the ASP, less applicable beneficiary deductible and coinsurance.

average wholesale price (AWP) List prices for drugs reported by pharmaceutical manufacturers and published in commercial clearinghouses such as *Redbook*, *Medi-Span*, *First Databank*, and Elsevier *Gold Standard (ProspectoRx)*. Each price is specific to the drug, strength, dose form, package size, and manufacturer or (re) labeler. Each price is specific to an 11-character national drug code (NDC) number that is comprised of the first five characters for the manufacturer or labeler, 4 characters for the drug and strength, and 2 characters for the package size.

benchmark (also: benchmark price) Government and other payers generally establish their payment for prescription drugs through formulas that start with a benchmark price. Some benchmarks are proprietary and not publicly available. For example, a state may set its Medicaid reimbursement rate at a benchmark price, such as average wholesale price (AWP) or wholesale acquisition cost (WAC), plus or minus a percentage. Some payment rates are subject to limits, such as through a maximum allowable cost (MAC) mechanism.

best price (BP) Regarding the Medicaid Rebate Program, Medicaid Best Price (BP) is the lowest manufacturer price paid for a prescription drug, regardless of package size, by any purchaser. BP is reported to CMS and states, but otherwise is confidential. Included in BP are: cash discounts, free goods that are contingent upon purchase, volume discounts, and rebates. Excluded from BP are prices paid by the federal government (i.e., prices to the Indian Health Service (IHS), Department of Veterans Affairs (VA), Department of Defense (DoD), the Public Health Service (PHS), 340B covered entities, Federal Supply Schedule, state pharmaceutical assistance programs, depot prices, and nominal pricing to covered entities).

Big 4 See federal Big 4.

biological product (biologic) Includes a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or they may be living entities, such as cells and tissues. Biologics are isolated from a variety of natural sources—human, animal, or microorganism—and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research and may be used to treat a variety of medical conditions for which no other treatments are available.

bona fide services Fee paid to an “entity” for an itemized service performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement and that is not passed in whole or in part to a client or customer of an entity, whether or not the entity takes title to the pharmaceutical.

book price See list price.

Brand name drug Manufacturer’s proprietary name for a drug. A brand name drug may or may not be the innovator product, and may have a generic equivalent in the market.

bundled (also: packaged, bundling) Packaging of drugs of different types for the purpose of provider payment, sometimes including provider services. Most commonly, a bundle of services is combined with drugs at a designated price, as in the case of ambulatory payment classifications (APCs), diagnosis-related groups (DRGs) and the dialysis prospective payment system. Alternatively, drug sales to providers from manufacturers may determine the net price of individual drugs in the bundle based on the on the sales volume of all drugs in the bundle.

capitation Method of payment for health services in which a health care provider is paid a fixed amount, usually prospectively, for each person on the provider’s patient roster, regardless of the quantity or nature of services actually provided.

carve-out pharmacy benefit Prescription and pharmacy services insurance coverage that is financially and administratively separated from the primary health care plan and typically administered under contract by a separate company, such as a pharmacy benefits manager (PBM). When care is capitated, a carve-out is a service or package of services not provided within the contract. Thus, it is carved out from the per member per month (PMPM) payment rate. A carve-out benefit also may be created when a provider cannot or will not provide some segment of care or is unavailable during periods of time when care may still be needed, such as urgent care.

case rate Flat fee paid for services based on patient characteristics, such as diagnosis. For this fee, the provider covers all of the services the patient requires for a specific period of time.

catalog price See list price.

Centers for Medicare & Medicaid Services (CMS) Formerly known as the Health Care Financing Administration (HCFA). This federal agency is responsible for administering Medicare and overseeing states’ administration of Medicaid.

chargeback (also: charge-back) Discounts handled through wholesalers. Manufacturers negotiate discounted prices with some purchasers who buy through wholesalers. Wholesalers can deliver the drugs at discounted prices, inform the manufacturers, and then request reimbursement from the manufacturers.

Center for Consumer Information and Insurance Oversight (CCIIO) Center within CMS that is responsible for implementation and for ensuring compliance with PPACA health reform rules.

class of trade (COT) Under federal law, customers such as buyers of pharmaceuticals that share similar profiles and attributes may be categorized into a COT to be eligible to receive similar pricing concessions, such as discounts and special offers. Most pharmaceutical companies have developed lists of similar customers and grouped them into different COTs. A manufacturer may have broad categories of COTs for most of its products (e.g., acute care, nonacute care, retail), but may allow a specific business unit to add an additional segment, such as long-term care (LTC), rather than include that sector in the nonacute COT.¹⁹¹ The business practice of offering various price discounts by COT was challenged by chain pharmacies in the 1990s. The U.S. Court of Appeals for the Seventh Circuit decided in July, 1999 (*In re Brand Name Prescription Drugs Antitrust Litigation*, No. 99-1167, 186 F.3d at 788), that the practice was not anticompetitive, and price concessions made by drug manufacturers by COT continue to this day.

coinsurance Percentage of the costs of medical services paid by the patient, usually at the point of care. This is a characteristic of indemnity insurance and preferred provider organization (PPO) plans. The coinsurance amount is often 20% of the cost of medical services after the deductible is paid.

comparative effectiveness Whereas most randomized controlled trials (RCT) compare active drug with placebo, comparative-effectiveness research compares clinical outcomes of alternative active drug therapies for the same condition. It is thought that results from comparative-effectiveness research may better inform health care decisions, reduce variability in care delivery, improve quality of care, improve efficacy, and improve efficiency.

Competitive Acquisition Program (CAP, and prescription drug CAP) Section 303 (d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required implementation of a CAP for Medicare Part B drugs and biologicals not paid on a cost or prospective payment system basis. CAP is an alternative to the average sales price (ASP) method (“buy and bill”) for acquiring certain Part B drugs that are administered incident to a physician’s services. CAP was implemented on July 1, 2006, and was postponed after December 31, 2008.

consumer-driven health plan (CDHP; also consumer-driven health care [CDHC]) Plans that include health spending accounts into which employers or individuals may contribute pre-tax dollars to be used for health care purchases. CDHPs are based in part on the theory that a beneficiary who is in control of their health care dollars will choose wisely how to spend and will be a good shopper for value and quality.

Consumer Price Index–Urban (CPI-U) Measure of the average change over time in prices paid by urban consumers for a market basket of consumer goods and services. The all-urban consumers group represents about 87% of the total U.S. population. It is based on the expenditures of almost all residents of urban or metropolitan areas including professionals, self employed, poor, unemployed, and retired persons as well as urban wage earners and clerical workers. Not included in the CPI-U are the spending patterns of persons living in rural nonmetropolitan areas, farm families, persons in the Armed Forces, and those in institutions, such as prisons and mental hospitals.

copayment The cost-share amount charged to an insured member for products or medical services, usually at the point of care. Copayment amounts are typically specified in the description of health plan member benefits, such as a fixed dollar amount for each prescription received (e.g., in a 3-tier pharmacy copayment design, \$5 for a generic prescription, \$15 for a preferred brand- name prescription, and \$30 for a non-formulary product).

cost-based reimbursement Payment made by a health plan or payer to health care providers based on the actual costs incurred in the delivery of care and services to plan beneficiaries. This method of paying providers is still used by some plans; however, cost-based reimbursement has largely been replaced by prospective payment and other payment mechanisms in Medicare and Medicaid.

cost sharing (also: see copayment, coinsurance) Method of reimbursement for health care services that holds the patient responsible for a portion or percentage of the charge, with an attending strategy to serve as a means of managing utilization; normally includes an annual deductible amount.

deductible Fixed amount of health care dollars of which a person must pay 100% before health benefits begin. Plans may include annual deductibles ranging from a few hundred to a few thousand dollars. Once the deductible is reached, the plan then pays up to 100% of approved amounts for covered services provided during the remainder of that benefit year.

Diagnosis Related Group (DRG) Used in Medicare's prospective payment system and by other public and private payers. DRGs classify patients into groups based on the principal diagnosis, treatments and other relevant criteria. Hospitals are paid the same amount for each case classified in the same DRG, regardless of the actual cost of treatment (but with provision for cost-outlier cases).

direct price (DP) Manufacturer's published catalog or list price for a pharmaceutical product to nonwholesalers. DP may or may not include standard volume discounts available to nonwholesaler customers. Similar to wholesale acquisition cost (WAC), DP may not represent actual selling prices, because it does not include important price adjustments, such as prompt pay, or other discounts, rebates, or reductions.

disproportionate-share hospital (DSH) Hospital with a disproportionately large share of low-income patients. Under Medicaid, states augment payment to these hospitals. Medicare inpatient hospital payments are also adjusted for this added burden.

doughnut hole Coverage gap in Medicare Part D prescription drug coverage, within which beneficiary is responsible for 100% of prescription drug cost. Coverage resumes when total prescription drug expenses reach \$6,955 (in 2013; indexed to the CPI), after which Medicare pays 80%, Part D plan pays 15%, and beneficiary pays 5% of prescription drug costs through the end of the calendar year.

dual eligible A person eligible for both Medicaid and Medicare coverage. Dual eligibles are automatically enrolled in Medicare Part D for prescription drug benefits.

Essential health benefits (EHBs) Per PPACA, essential health benefits must cover at least the following 10 categories of services: ambulatory patient services; emergency services; hospitalizations; maternity and newborn care; mental health and substance use disorder services, including behavior health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

estimated acquisition cost (EAC) Federal regulations (at 42 CFR § 447.512) require, with certain exceptions, that each State Medicaid agency's reimbursement for covered outpatient drugs not exceed (in the aggregate) the lower of the estimated acquisition cost for drugs plus a reasonable dispensing fee or the provider's usual and customary charge to the public for the drugs. Estimated Acquisition Cost represents state Medicaid agency's estimate of the price generally paid by pharmacies

for a pharmaceutical. This figure is often meant to represent a calculation across all pharmacies of the mean or median actual acquisition cost (AAC). As of March 2007, WAC was used in some way by 11 state Medicaid programs, but AWP was the predominant basis of pharmacy provider reimbursement for drug acquisition cost. PPACA replaced EAC with AAC.

Evidence based medicine The practice of selecting treatment based on scientific evidence that assesses comparative efficacy and risk in particular clinical circumstances and patient populations.

exchange (health insurance exchange) A state-based structure, mandated by PPACA, that facilitates enrollment of individuals, families and businesses in health coverage that meets EHB standards.

federal Big 4 The 4 largest purchasers of pharmaceuticals within the federal government: Department of Veterans Affairs (VA), Department of Defense (DoD), Public Health Service (PHS), and Coast Guard. These 4 federal agencies have the right to purchase their pharmaceuticals from the Federal Supply Schedule (FSS), as does every other federal agency. However, the Big 4 often obtain pricing below the FSS on brand-name drugs because these drugs are subject to a maximum statutory price called the federal ceiling price (FCP).

federal ceiling price (FCP) Maximum price that manufacturers can charge for Federal Supply System (FSS)-listed brand-name drugs to the Big 4—Department of Veterans Affairs (VA), Department of Defense (DoD), Public Health Service (PHS), and Coast Guard—even if the FSS price is higher. The FCP must be at least 24% below the nonfederal average manufacturer price (non-FAMP). FCP prices are not publicly available.

Federal Supply Schedule (FSS) Collection of multiple-award contracts used by federal agencies, U.S. territories, Indian tribes, and other specified entities to purchase supplies and services from outside vendors. FSS prices for the pharmaceutical schedule are negotiated by the Department of Veterans Affairs (VA) and are based on the prices that manufacturers charge their "most-favored" nonfederal customers under comparable terms and conditions. Because terms and conditions can vary by drug and vendor, the most-favored customer price may not be the lowest price in the market. FSS prices are publicly available.

federal upper limit (FUL) Price calculated and published by the Centers for Medicare & Medicaid Services (CMS) as the maximum amount that a state Medicaid program can pay for a multiple-source (generic) pharmaceutical. Sometimes called federal MAC or FED MAC.

follow-on biologic drug (biosimilar) A biologic that is comparable to, but which may or may not be clinically or legally interchangeable with, a brand-name innovator biologic whose patent has expired.

formulary List of drugs considered by physicians and pharmacy staff of a health care organization as preferred for use in treating patients served by the organization.

open or unrestricted formulary List of preferred drugs that is not necessarily tied to member cost-share. An open formulary may have a single copayment or coinsurance amount for all drugs or, more typically, is associated with 2-tiered copayment in which there is a copayment (e.g., \$5.00) for all generic drugs and a higher copayment (e.g., \$20) for all brand drugs whether listed on the formulary or not. Therefore, physicians prescribing from an open formulary are not restricted in the products they may prescribe.

closed formulary Exclusive lists of covered drugs that limit prescribers and health plan members to only some of the commercially available products in each therapeutic class. Drugs not listed as preferred (i.e., nonformulary drugs) are not covered by the payer. Patients without prior authorization (PA) typically pay 100% of the provider's charge for non-formulary drugs.

partially closed/incentive formulary Nonpreferred (i.e., nonformulary) drugs have a higher member cost-share, such as found in multiple-copayment tiers (e.g., 3-tiered copayment designs). A 4-tiered copayment design may have a generic drug (tier 1) copayment, preferred drug (tier 2) copayment, non-preferred drug (tier 3) copayment, and the highest copayment or coinsurance (50%) for cosmetic or other "lifestyle" drugs or perhaps a 4th cost-share tier (e.g., 20%) for injectable or other specialty pharmaceuticals.

generic drug Identical to a brand-name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, the FDA requires many rigorous tests and procedures to ensure that the generic drug can be substituted for the brand-name drug. The FDA bases evaluations of substitutability, or "therapeutic equivalence," of generic drugs on scientific evaluations. The FDA Orange Book provides ratings of equivalence [A-rated] and non-equivalence for generic substitution. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand-name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand-name product.

generic substitution (1) A payer requirement that therapeutically equivalent generic drugs, when available, be substituted for brand-name drugs unless the prescribing physician indicates 'do not substitute'; and (2) State laws governing when and how pharmacists may substitute therapeutically equivalent generic drugs for brand-name drugs.

global price (also: global fee) Total prospectively determined amount that is paid for a specific set of services, such as obstetrical services that encompass prenatal, delivery, and postnatal care.

group purchasing organization (GPO) Organization that pools purchasers working together to provide larger potential purchases of particular goods and/or services and therefore lower unit costs.

guidelines (practice guidelines, clinical guidelines, treatment guidelines, administrative guidelines, protocols) Systematic sets of rules, which may be clinically or administratively based, for choosing among alternate drug therapies. For example, a clinically based guideline may recommend that a drug therapy with fewer side effects be tried before a more potent therapy is prescribed. An administratively based guideline may recommend initial trial of a generic multiple source drug before use of a single source brand drug.

health maintenance organization (HMO) Form of health insurance in which its members and/or members' employers prepay a premium for the HMO's health services, which generally include inpatient and ambulatory care. For the patient, it means reduced out-of-pocket costs (i.e., no deductible), no paperwork (i.e., insurance forms), and only a small copayment for each office visit to cover the paperwork handled by the HMO. There are several different types of HMOs.

group model The HMO contracts with a physician group, which is paid a fixed amount per patient to provide specific services. The administration of the group practice then decides how the HMO payments are distributed to each participating physician. This type of HMO is usually located in a hospital or clinic setting and may include a pharmacy. These physicians usually do not have any fee-for-service (FFS) patients.

hybrid model Combination of at least 2 managed care organizational (MCO) models that are melded into a single health plan. Because its features do not uniformly fit 1 model, it is called a hybrid.

independent practice association (IPA) model The IPA contracts with independent physicians who work in their own private practices and see fee-for-service (FFS) patients as well as HMO enrollees. Physicians belonging to the IPA may accept financial risk that the care needed by patients for whom they are responsible will fall within a pre-established per member per month (PMPM) budget.

network model Network of group practices under the administration of one HMO.

point-of-service (POS) model Sometimes referred to as an “open-ended” HMO. The POS model is one in which the patient can receive care by physicians who are either contracted with the HMO or who are not contracted. Physicians not contracted with the HMO who see an HMO patient are paid according to the services performed. Thus, the patient has an incentive to use contracted providers due to the fuller coverage offered for contracted care.

staff model All physicians in a staff model HMO are in a centralized site where all clinical and perhaps inpatient and pharmacy services are offered. The HMO holds the tightest management reigns in this setting because none of the physicians traditionally practice on an independent fee-for-service (FFS) basis. Physicians are more likely to be employees of the HMO in this setting because they are not in a private or group practice.

Healthcare Common Procedure Coding System (HCPCS) Federal coding system for medical procedures. The HCPCS includes current procedural terminology (CPT) codes (Level I), national alpha-numeric codes (Level II), and local alpha-numeric codes (Level III). National codes are developed by the Centers for Medicare & Medicaid Services (CMS) to supplement CPT codes and include physical services not included in CPT as well as nonphysician services such as ambulance, physical therapy, and durable medical equipment (DME). Local codes are developed by local Medicare carriers to supplement the national codes. J-codes are a subset of the HCPCS Level II code set used to identify certain drugs and other items.

high deductible health plan (consumer driven health plan) A health plan that requires the beneficiary to pay a high amount out-of-pocket before coverage for most health care benefits become available. Such a plan may be paired with a Health Savings Account (HSA) from which the beneficiary may pay for covered health care products and services on a pre-tax basis.

home-infusion pharmacy Pharmacy specializing in supplying members with home-infusion therapy medications and supplies.

house brand Private-labeled prescription drugs, repackaged for sale. See repackaged.

Independent Payment Advisory Board A PPACA-created board with the authority to limit Medicare spending growth, but not including rationing of care, tax increases, change in premiums or in cost-sharing, or reduction in low-income subsidies.

inpatient Pertaining to the treatment of patients admitted to a hospital bed.

intermediary Entity contracted to a purchaser for provision of products and/or services to beneficiaries or providers, with a purchaser-defined level of authority in the handling of this responsibility and responsibility to the purchaser for performance.

list price Published price that is not an actual transaction price. Certain pharmaceutical transactions, such as setting payment rates to pharmacies, may be based on list prices. The average wholesale price (AWP) and the wholesale acquisition cost (WAC) are examples of list prices.

long-term care (LTC) Services ordinarily provided in a skilled nursing, intermediate care, personal care, supervisory care, or elder care facility.

Low Income Subsidy (LIS) Government support for premiums and cost-share available to certain low income people enrolled in the Medicare Part D program.

mail-service option Pharmacy benefit specifying that all or certain drugs, such as maintenance drugs, may be obtained from a designated mail-service pharmacy, usually provided in a 2- or 3-month supply.

managed care organization (MCO) Generic term applied to a managed care plan. They also are called health maintenance organizations (HMOs), preferred provider organizations (PPOs), and exclusive provider organizations (EPOs), although the MCO may not conform exactly to any of these formats.

maximum allowable cost (MAC) Cost management program that sets upper limits on the payment for equivalent drugs available from multiple manufacturers. MAC is the highest unit price that will be paid for a drug and is designed to increase generic dispensing, ensure that the pharmacy dispenses economically, and control future cost increases by taking advantage of competitive pricing among multiple-source drugs.

Medicaid State-operated and administered program that is funded jointly by the federal and state governments. Medicaid provides medical benefits for certain indigent or low-income persons in need of health and medical care. The program is authorized by Title XIX of the Social Security Act. Within broad federal guidelines, states determine the benefits covered, program eligibility, rates of payment for providers, and methods of administering the program.

Medicaid Drug Rebate Program Drug manufacturers are required to enter into national rebate agreements, based on a statutory rebate formula, with the Department of Health and Human Services before Medicaid will pay for manufacturers' drugs dispensed to Medicaid patients.

Medicare National program of health insurance operated by the Centers for Medicare & Medicaid Services (CMS) on behalf of the federal government since its creation by Title XVIII—Health Insurance for the Aged in 1965 as an amendment to the Social Security Act. Medicare provides health insurance benefits primarily to persons older than 65 years of age and others who are eligible for Social Security benefits and covers the cost of hospitalization, medical care, prescription drugs, and some related services.

Part A Insurance program (also called Hospital Insurance program) that provides basic protection against the costs of hospital and related post-hospital services for individuals aged 65 years or older who are eligible for retirement benefits under the Social Security or Railroad Retirement System. Part A pays for inpatient hospital, skilled nursing facility (SNF), and home health care. The Hospital Insurance program is financed from a separate trust fund and primarily funded with a payroll tax levied on employers, employees, and the self-employed.

Part B Medicare component that provides benefits to cover the costs of physicians' professional services, whether the services are provided in a hospital, physician's office, extended-care facility, nursing home, or insured's home.

Part C Previously called Medicare + Choice when it was created by the Balanced Budget Act of 1997, it is now called Medicare Advantage. (See Medicare Advantage.)

Part D The Medicare component that provides benefits to cover the costs of outpatient prescription drugs (OPDs). Benefits commenced on January 1, 2006, and are administered through private health plans.

Medicare Advantage Previously called Medicare + Choice, legislation in which Medicare expanded the number of eligible private and public entity risk contractors as part of the Balanced Budget Act of 1997. Current health maintenance organizations (HMOs) and competitive medical plans (CMPs) are automatically transitioned to Medicare Advantage but must comply with new rules, while provider-sponsored organizations (PSOs) also are allowed to accept Medicare risk. A Medicare Advantage offering pharmacy benefits is called an MA-PD.

Medicare Prescription Drug, Improvement, and modernization Act of 2003 (MMA) This law created Medicare part D, increased the Part B deductible, expanded private Medicare Advantage plans, and expanded Health Savings Accounts.

MedPAC The Medicare Payment Advisory Commission (MedPAC) is an independent Congressional agency established by the Balanced Budget Act of 1997 (P.L. 105-33) to advise the U.S. Congress on issues affecting the Medicare program. The Commission's statutory mandate is broad: In addition to advising the Congress on payments to private health plans participating in Medicare and providers in Medicare's traditional fee-for-service program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare.¹⁹²

multiple-source brand Refers to the brand version of a drug when it is available in both brand-name and generic versions from a variety of manufacturers.

multiple-source drug Drug available in both brand-name and generic versions from a variety of manufacturers.

National Drug Code (NDC) Defined officially as a 10-character number by the FDA but commonly implemented in claims administration systems as an 11-character number. The NDC number is divided into three segments: the first five characters for the labeler (which may or may not be the manufacturer), four characters for the drug and strength, and the last two characters to describe the package size.

net price Price, after discounts are deducted, paid at different levels of the channels of prescription drug distribution (e.g., purchaser to provider, provider to wholesaler, and wholesaler to manufacturer).

net product revenue (for calculation of average sales price) Sum of a manufacturer's volume discounts, prompt-pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927 of the Social Security Act) for the most recently available 12-month period associated with all sales included in the average sales price (ASP) reporting requirements.

nominal price and nominal price exception (or exclusion) Nominal price pertains to manufacturer reporting to CMS of AMPs for Medicaid rebate purposes and includes any price less than 10% of the AMP in the same quarter for which the AMP is computed. The final rule implementing the Deficit Reduction Act of 2005 (DRA), CMS-2238-FC, limited the nominal price exception for manufacturer reporting of AMPs to CMS to a smaller list of purchasers: 340B-eligible entities, intermediate care facilities for the mentally retarded, and state-owned or state-operated nursing facilities.

nonfederal average manufacturer price (non-FAMP) Average price paid to a manufacturer by wholesalers for drugs distributed to nonfederal purchasers. Under federal law, the Big 4 are entitled to discounts on brand-name drugs of at least 24% off the non-FAMP. Non-FAMP is not publicly available.

Omnibus Budget Reconciliation Act of 1990 (OBRA 90) Medicaid Drug Rebate Program created by the Omnibus Reconciliation Act of 1990 (OBRA 90) that added Section 1927 to the Social Security Act, effective January 1, 1991. The law requires that manufacturers enter into an agreement with the Centers for Medicare & Medicaid Services (CMS) to provide rebates for their drug products that are paid for by Medicaid. Manufacturers that do not sign an agreement with CMS are not eligible for federal Medicaid coverage of their product(s). Except for statutory limitations, state Medicaid programs must provide coverage and reimbursement for all covered outpatient drug products manufactured by companies that have entered into a rebate agreement with CMS.

Orange Book *Approved Drug Products with Therapeutic Equivalence Evaluations* (U.S. Department of Health and Human Services and Food and Drug Administration), also known as the *Orange Book*. Publication that identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act. Patent listings can be found in this online book, which is updated frequently throughout the year, at: <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>.

own use Term developed in case law that is related to class of trade (COT) pricing in the pharmaceutical industry. The Non-Profit Institutions Act (15 U.S.C.A. Section 13c), enacted 2 years after the Robinson-Patman Act, exempts “purchases of their supplies for their own use by hospitals, and charitable institutions not activities may include some or all of the following: benefit plan design, creation/administration of retail and mail service networks, claims processing, and managed prescription drug care services such as drug utilization review, formulary management, generic dispensing, prior authorization (PA), and disease and health management.

plan sponsor See payer.

preferred drug list (PDL) Used interchangeably with “formulary,” a listing of medications that beneficiaries may readily access through their health plans. Non-PDL medications may not be accessible, may carry a higher cost-share amount, or may be of a health maintenance organization (HMO), any sale of drugs to a member falls within the basic function of the HMO; therefore, the purchase of drugs by an HMO for dispensing to its members is for its “own use” and within the Non-Profit Institutions Act exemption. Hospitals and health systems that operate ambulatory care pharmacies that dispense drugs to patients who are not hospital or health system employees or members typically maintain separate prescription drug inventories so as not to violate the “own use” exemption.¹⁶³

patient assistance program (PAP) Program administered by a pharmaceutical company or its agent that provides financial assistance with prescription drug costs. PAPs offer free and discounted prescription drugs to those who qualify.

patient cost-share See cost-share, copayment, and coinsurance.

pay for performance Use of provider payment incentives to encourage and reinforce the delivery of evidence-based practice to promote better and more efficient patient outcomes.

payer (also: purchaser, plan sponsor, third-party payer, insurer) Public or private organization that pays or insures health or medical expenses on behalf of beneficiaries or recipients who pay a premium for this coverage in all private and some public programs. The payer pays medical or pharmacy claims on behalf of covered individuals, which are called third-party payments.

payment rate With respect to a purchaser-to-provider transaction, net amount paid for the product and/or service rendered.

per diem reimbursement Reimbursement to an institution (usually a hospital) based on a set rate per day rather than on charges accrued. Per diem reimbursement can be varied by service (e.g., medical/surgical, obstetrics, mental health, intensive care) or can be uniform regardless of intensity of services.

pharmacy benefit management (PBM) companies Organizations that manage pharmaceutical benefits for managed care organizations (MCOs), other medical providers, or employers. PBMs contract with clients who are interested in optimizing the clinical and economic performance of their pharmacy benefit. PBM accessible only if prior authorization (PA) is obtained.

preferred provider organization (PPO) A PPO plan has a network of providers that have agreed to contractually specified reimbursement for covered benefits with the organization offering the plan; and provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and is offered by an organization that is not licensed or organized under state law as an HMO.

prescription drug plan (PDP) Standalone PDPs provide Medicare Part D benefits in a traditional fee-for-service (FFS) Medicare program and to beneficiaries in Medicare Advantage plans that do not offer a prescription drug benefit.

price concession Discount or rebate offered with respect to the purchase of a product or service, conditional upon the purchaser's compliance with terms and conditions of the offer.

price transparency Disclosure of price-related information by an entity to persons or organizations outside of that entity.

prior authorization (PA) Sometimes called "prior approval." The physician or pharmacy must generally request approval from the health plan through a designated process to obtain coverage for the beneficiary and reimbursement to the provider.

private insurer See payer.

prompt-pay discount Discount provided for the payment of an invoice within a designated time, often 10, 30, or 60 days subsequent to product delivery.

prospective payment Payment received before care is delivered. It gives the provider organization a financial incentive to use fewer resources because they are allowed to keep the difference between what is prepaid and what is actually used.

provider Any supplier of services (i.e., physician, pharmacist, case management firm).

provider acquisition cost Estimate of the actual acquisition cost (AAC) of providers.

provider purchase price The actual acquisition cost (AAC) of providers.

Public Health Service (PHS) 340B ceiling price Calculated by the Office of Pharmacy Affairs (OPA) within the Department of Health and Human Services (DHHS), maximum price that manufacturers can charge covered entities participating in the 340B Drug Pricing Program of the PHS. The 340B discount is calculated by using the Medicaid rebate formula and is deducted from the manufacturer's selling price, rather than paid as a rebate.

published price See list price.

purchaser See payer.

rebate Monetary amount returned to a payer from a prescription drug manufacturer based on pharmaceutical use by a covered person or purchases by a provider.

reference price Limits reimbursement for a group of drugs with similar therapeutic application but different active ingredients to the price of the lowest-cost drug within the group (the reference standard). Patients may purchase drugs other than the reference product, in which case they pay the difference between the retail price and the Reference Price.

reimbursable (also: reimbursement) Process by which health care providers receive payment for their services is sometimes referred to as "reimbursement." Because of the nature of the health care environment, providers are often reimbursed by third parties who insure and represent patients. A product or service that a health care provider administers to a patient and for which necessary approvals have been given becomes reimbursable.

repackaged Prescription drug taken from its original manufacturer container and placed into another labeled container for dispensing.

retail class of trade The Affordable Care Act revised the definition of AMP by replacing the term "retail pharmacy class of trade" with "retail community pharmacy." AMP is now defined as: "average price paid to a manufacturer for the drug by wholesalers for drugs, distributed to retail community pharmacies and retail community pharmacies that purchase drugs direct from the manufacturer." The Affordable Care Act further defines "retail community pharmacy" as follows: The term "retail community pharmacy" means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. It does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

RxNorm: RxNorm is a normalized naming system for generic and branded drugs; and a tool for supporting semantic interoperability between drug terminologies and pharmacy knowledge base systems. RxNorm contains the names of prescription and many over-the-counter drugs available in the United States. The National Library of Medicine (NLM) produces RxNorm. (see: <http://www.nlm.nih.gov/research/umls/rxnorm/overview.html>) CMS requires Part D vendors to submit proposed drug lists using RxNorm, not NDC. Under health reform, health plans may be required to do the same. (see BCBSA letter to CMS, 12/21/12: http://ehbc.wpengine.netdna-cdn.com/wp-content/uploads/2013/01/BCBSA_comment_letter_EHB_AV_Accreditation_NPRM_12_21_12-Final.pdf)

self-insurance: See administrative services only.

single-source brand Drug under patent protection that is sold under a brand name and is thus available from only 1 manufacturer (or occasionally from other manufacturers under license from the patent holder). No generic version is available.

site of care Site at which health care services and products are administered to the patient (e.g., hospital, physician office, pharmacy, patient's home).

specialty pharmacy Pharmacy that dispenses generally low-volume and high-cost medicinal preparations (specialty pharmaceuticals) to patients who are undergoing intensive therapies for illnesses that are generally chronic, complex, and potentially life threatening (e.g., rheumatoid arthritis, multiple sclerosis, hemophilia). These therapies often require specialized delivery and administration.

stakeholder A party of interest. With respect to prescription drugs, stakeholders include but are not limited to purchasers, group purchasing organizations (GPOs), wholesalers, pharmaceutical manufacturers, providers, and patients.

step therapy A health plan or pharmacy benefit manager (PBM) may require a beneficiary to try 1 drug before the plan will pay for another drug. A principal purpose of step therapy is to reduce the average cost for treating a given condition (e.g., hypertension, heartburn, or depression), requiring beneficiaries to use an equally effective, lower-cost drug before coverage of a higher-cost, second-line drug. The health plan or other payer may require evidence of therapeutic failure (e.g., intolerance due to side effects) before coverage of the second-line drug.

supplemental rebate A rebate over and above the statutory rebate that States may negotiate with pharmaceutical manufacturers.

therapeutically equivalent product Drug products containing different chemical entities that should provide similar treatment effects as well as the same pharmacological action or chemical effect when administered to patients in therapeutically equivalent doses. Per the *Approved Drug Products With Therapeutic Equivalents* (also known as the *Orange Book*), drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling. Drug products are considered pharmaceutical equivalents if they contain the same active ingredient(s), are of the same dosage form and route of administration, and are identical in strength or concentration.

therapeutic maximum allowable cost (TMAC) Managed care intervention that establishes a defined benefit dollar amount per therapeutic procedure or indication, such as \$0.75 per day of drug therapy for heartburn based on the omeprazole over-the-counter (OTC) price or \$0.50 per day of therapy for allergic rhinitis based on the market price of loratadine OTC.

third-party administrator (TPA) Organization that provides administrative services to group benefit plans that may include premium accounting, claims adjudication and payment, claims utilization review (e.g., for medical necessity), maintenance of employee eligibility records, and negotiations with insurers that provide stop-loss protection for large claims individually ("specific") or collectively ("aggregate"). TPAs do not themselves assume insurance risk.

third-party payer (also: third-party carrier) Public or private organization (such as Blue Cross and Blue Shield, Medicare, Medicaid, commercial insurer, self-insured employer, Taft-Hartley Trust, or Multiple Employer Trust) that pays for or underwrites coverage for health care expenses for an individual or group. The individual enrollee generally pays a premium for coverage in all private and some public health insurance programs, and the organization pays claims on the patient's behalf.

traditional community pharmacy (retail community pharmacy) Any place under the direct supervision of a pharmacist where the practice of pharmacy occurs or where prescription orders are compounded and dispensed other than a hospital pharmacy, limited service pharmacy, or mail service (mail order) pharmacy.

usual and customary (U & C) price The price for a given drug or service that a pharmacy or other provider would charge a cash-paying customer without the benefit of insurance provided through a payer or intermediary with a contract with the provider.

usual, customary, and reasonable (UCR) Amount determined to be “reasonable” (acceptable) by comparing the U & C charges among providers in a given geographic region. UCR prices are commonly used by traditional health insurance companies as the basis for physician reimbursement.

VA national contract price Price obtained by the Department of Veterans Affairs (VA) through competitive bids from manufacturers for select drugs in exchange for their inclusion on the VA formulary. Because the VA is entitled to federal ceiling prices (FCPs) under federal statute, VA national contract prices are even lower than FCP prices and are often the lowest prices in the nation.

volume purchase agreement Manufacturer agreement to sell prescription pharmaceuticals at a given price that is subject to additional discounts or rebates conditional on the purchase of a fixed quantity of product over a defined time period.

wholesale acquisition cost (WAC) Price paid by a wholesaler for a drug purchased from the wholesaler’s supplier, typically the manufacturer of the drug. Publicly disclosed WAC amounts may not reflect all available discounts, such as prompt-pay (cash) discounts.

wholesaler Firm involved in logistics function (assembling, sorting, and redistributing) in the channel of distribution for pharmaceuticals. Wholesalers purchase goods from manufacturers and redistribute them to purchasers, who may be pharmacies, physicians, or other types of providers.

widely available market price (WAMP) Price that a prudent physician or supplier would pay for the drug or biological, taking into account the discounts, rebates, and other price concessions routinely made available for such drugs or biologicals. WAMP would not be a list price that commonly is discounted, but would be the purchase price net of discounts, rebates, and price concessions routinely available to prudent purchasers.

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